APPENDIX C

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR LABORATORIES AND LABORATORY SERVICES

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR LABORATORIES AND LABORATORY SERVICES

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POLICY FOR CONDUCTING SURVEYS

Survey protocols and interpretive guidelines are established pursuant to pertinent sections of the Social Security Act, the Public Health Service Act, and the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 CFR Part 493) to provide guidance to personnel conducting surveys of laboratories. The protocols and guidelines clarify and/or explain the intent of the regulations and are required for use by all surveyors assessing laboratory performance based on Federal requirements. The same survey protocols are used by the regional office (RO) and/or State Agency (SA) surveyors and therefore are written to address the surveyor.

The following protocols represent an outcome-oriented method to be used to conduct the survey. The focus of the survey is to assess how the laboratory monitors its operations and ensures the quality of its testing. The intended use of these protocols is to promote consistency in the approach to the survey process and to ensure that a laboratory's operations are reviewed in a practical, efficient, and effective manner so that at the completion of the survey there is sufficient information to make compliance decisions. While the purpose of the protocols and guidelines is to provide direction in preparing for the survey; in conducting the onsite survey; and for analyzing, evaluating, and documenting survey findings; the surveyor's professional judgement is the most critical element in the survey process.

HCFA's objective is not only to determine the laboratory's regulatory compliance but also to assist regulated laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. HCFA promotes the use of an educational survey process. It is the surveyor's objective, using professional judgement, to determine, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel, and review of the laboratory's relevant documented records, whether it is producing accurate, reliable, and timely (quality) test results. Regardless of the manner in which the surveyor approaches assessing the laboratory's operation and test performance, the primary objective is to determine whether or not the laboratory meets the CLIA requirements. The surveyor meets this objective by employing an outcome-oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

Surveyors must make every effort to minimize the impact of the survey on laboratory operations and patient care activities, and to accommodate staffing schedules and departmental workloads as much as possible. In facilities providing direct patient care, e.g., physician offices, clinics, residential care facilities, and hospitals, respect patient privacy, maintain confidentiality, and do not interrupt or interfere with patient care.

When performing a survey that includes Provider-Performed Microscopy (PPM) procedures, the appropriate requirements in 42 CFR Part 493, Subparts C, H, J, K, M, P, and Q apply. (See page C-19 for conducting surveys of certificate for PPM Procedures.)

(See page C-18 for conducting surveys of partially accredited specialties/subspecialties; page C-19 for conducting surveys of waived tests; and page C-18 for conducting surveys of multiple testing sites under one certificate.)

THE OUTCOME-ORIENTED SURVEY PROCESS

The principal focus of the survey is the effect (outcome) of the laboratory's practices on patient test results and/or patient care. The Outcome-Oriented Survey Process is intended to direct the surveyor to those requirements that will most effectively and efficiently assess the laboratory's ability to provide accurate, reliable, and timely test results.

In an outcome-oriented/quality improvement survey process, the surveyor needs to review and assess the overall functioning of the laboratory and evaluate its ability to perform quality testing. The quality assurance requirements of the laboratory regulations (42 CFR Part 493, Subpart P) are an appropriate guide for organizing the surveyor's review. Select a cross-section of information (from all aspects of the laboratory's operation) for review to assess the laboratory's ability to produce quality results as well as its ability to identify and correct problems. Emphasis should be placed on overall laboratory performance and the structures and processes contributing to the reliability of the testing. Review the selected cross-section of information to see if the laboratory has established and implemented appropriate ongoing mechanisms for monitoring and evaluating its practices and solving its problems. If the laboratory has met CLIA requirements and if your evaluation does not warrant a more in-depth review, conclude the survey and ask if the laboratory has any questions about CLIA requirements.

Although Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, includes guidelines and instructions for each regulatory requirement and encompasses all types of laboratory facilities, use only those portions applicable to the laboratory=s operations and complexity of testing performed.

I. IDENTIFYING SOURCES OF INFORMATION

A. Announced and/or Unannounced Surveys.--Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced inspections/surveys. Complaint or revisit surveys must be conducted on an unannounced basis. (See §6106 for policy regarding announced and/or unannounced surveys.)

When applicable, the laboratory may be notified by telephone or mail. Notification may include the actual date and time of the survey. Request that the laboratory notify the inspecting agency (e.g., SA or RO) if its laboratory operations are not conducted during usual hours of operation or only on specific days and times. Whenever possible, conduct surveys during the laboratory's routine hours of operation. Request notification if the certificate status has changed. If the laboratory has applied for a certificate of accreditation, ask the laboratory to provide documentation (e.g., written verification from the accrediting organization) of its accredited status. If the laboratory changes its level of service to PPM procedures or waiver before the survey, it should inform the inspecting agency.

B. Scheduling Surveys.--Scheduling the survey is a different function than announcing the survey to the laboratory. Schedule the recertification survey at least 6 months prior but no earlier than 12 months prior to the expiration of the laboratory's current certificate. Any new laboratories, and if at all possible, complaint and validation surveys in the geographic area should be worked into this schedule. For efficiency when scheduling, attempt to cluster surveys geographically.

Establish a date and time for the survey once the schedule has been completed. This is the schedule followed as part of the survey work load. If a laboratory operates more than one shift or location, schedule survey hours to include a representative cross-section of shifts or locations, as necessary. For either an initial CLIA or recertification CLIA survey, an unannounced survey may be performed after one canceled appointment. The laboratory must be informed of this when notified of the original survey.

To enhance survey effectiveness and efficiency:

1. Except in the case of complaints, consider mailing the following to laboratories before the scheduled survey date and request the laboratory to complete:

o Form HCFA-1513 or Form HCFA-855 as needed. (See §2005.) Consult the annual laboratory registry or CLIA/OSCAR database to assist with determining whether the owner has had a laboratory certificate revoked within the last 2 years;

o Form HCFA-209 (personnel) with directions for completing or updating information, adding new personnel or changes in positions or status; and

o Form HCFA-116 (application) or SA form for updating or verifying tests, specialties, and annual test volume performed.

2. Request the following information be accessible and retrievable at the time of survey:

o Standard operating procedure manual with all test procedures (i.e., package inserts and supplemental information, as necessary);

o Reference laboratories= client services manual, if applicable;

o Records of tests referred to other laboratories;

o Personnel records including training, certificates, degrees, continuing education, experience, duties/responsibilities, and changes;

o Quality control records, including:

- Remedial action information;
- Statistical limits; and
- Instrument maintenance records.

o Proficiency testing (PT) reports, including:

- Test runs with PT results;
- Direct printouts; and
- Remedial actions for unsatisfactory results.

o Quality assurance plan and documentation;

o Safety information;

o Copy of application (Form HCFA-116) and any changes including annual test volume; (See page C-17 for counting test.) and

- o Patient testing records:
  - Requisition (patient charts may be used);
  - Work records (direct printouts); and
  - Patient test reports (patient charts may be used).

C. Pre-Survey Preparation.--Prior to each survey, review the laboratory's file, including the CLIA database information and number of sites under its certificate, to determine the size of the survey team and the expected time required for the survey. Scope and volume of testing and test complexity will influence the amount of time needed to conduct the survey.

1. Personnel.--Include the completed or updated Form HCFA-209 in each survey package. Use this information during the onsite survey to evaluate positions currently held by employees in accordance with the requirements. Focus on new personnel since the last survey.

2. Services Offered.--Review the CLIA application, the list of tests and specialties, and any correspondence from the laboratory to determine the complexity of tests performed. Ascertain whether the laboratory has changed complexity of testing within specialties/subspecialties, or added or deleted tests or services since the last survey.

3. PT.--Review PT records to ensure that the laboratory is enrolled and participating in an approved program for each PT regulated analyte, specialty, and subspecialty for which testing is performed. Note any unacceptable or unsatisfactory scores. Use this information to target particular tests for review during the survey.

4. File Review.--Evaluate the laboratory's ability to maintain compliance between surveys by reviewing its file for:

- o Previous survey results and plans of correction, noting patterns, number, and nature of deficiencies, and dates of correction;

- o Enforcement action(s) taken or in progress, i.e., limitations of the certificate or voluntary withdrawal of a specialty, subspecialty, or analyte/test due to unsuccessful proficiency testing or loss of qualified personnel; and

- o Complaint allegations noting frequency, significance, severity and, if substantiated, the resolution;

II. ENTRANCE INTERVIEW

The entrance interview sets the tone for the entire survey. Be prepared, courteous, and make requests, not demands. Upon arrival, the surveyor presents the appropriate identification, introduces other team members, informs the facility=s administrator, director, or supervisor of the purpose of the survey, the time schedule, and explains the survey process. Identify a contact person and establish a communication level based on the degree of technical knowledge of the contact person. .

If the laboratory consists of multiple testing sites, verify all information concerning testing performed at each site. If one or more sites does not meet the multiple site exceptions in the regulations (42 CFR 493.35(b)), explain the reason and have the administrator/director complete Form HCFA-116 for each applicable site. (See page C-18 for conducting surveys of multiple testing sites under one certificate.)

Inform the laboratory that the survey will include a tour of the facility, record reviews, observations, and interviews with personnel involved in the pre-analytic, analytic, and post-analytic processes. Establish personnel availability and discuss approximate time frames for survey completion. Determine whether the deficiencies, when identified, are to be discussed with testing personnel, and explain that an exit conference may be held to discuss survey findings. Refer to Chapter 6, §§6124 and 6126 for additional information regarding exit conferences.

Request that the laboratory collect any documents, records, or information that may be needed to complete the survey, and solicit and answer any questions the laboratory may have concerning the survey process.

III. INFORMATION GATHERING

The techniques for information gathering include observation, interviews, and record review and are usually performed concurrently. The information gathering process is critical in the assessment of quality laboratory testing. Evaluate the laboratory's operations without being excessive. As each laboratory is unique in the services offered, the order of gathering information may be different for each survey. The timing for observing testing and the availability of staff for interview may determine the sequence of the survey.

Consider the laboratory's compliance history (deficient practices and Plans of Correction). Verify the correction and continued compliance with all previously cited deficiencies. Pay particular attention to deficiencies that the laboratory has failed to correct. Refer to enforcement requirements in 42 CFR Part 493, Subpart R.

A. Organizing the Survey.--Consider the following variables when making determinations for organizing the survey and the areas to be reviewed:

- Purpose of the Survey:
  - Initial or recertification (refer to § §6112-6114 regarding CLIA recertification using the Alternative Quality Assessment Survey (AQAS));
  - Complaint;
  - Follow-up;
  - Validation; and/or
  - AQAS verification (refer to '6114).
- Pre-survey Information:
  - Problematic PT;
  - Previous survey deficiencies; and/or
  - Complaints.

- o Size and Organization of the Laboratory:
  - Type of instruments/test procedures;
  - Number of supervisors;
  - Number of testing personnel;
  - Number of testing sites;
  - Number of shifts that testing is performed;
  - Scheduling of testing (e.g., Stat, daily, weekly);
  - Number of specialties/subspecialties;
  - Record availability; and/or
  - Types of patients/clients served.

B. Observation of Facilities and Processes.--Observe the laboratory=s physical layout. These observations should include specimen collection and processing, "prep" and clean-up areas, testing and reporting areas, and storerooms. Whenever possible, observe specimen processing and test performance, noting information which would precipitate revisiting an area, interviewing personnel, or requesting records for review. Observe and verify that reagents, kits, and equipment correlate with test menu and clients served. Also observe whether staffing appears adequate for test volume.

The RO and/or the SA schedules the survey date/time to observe personnel performing specimen processing, testing, and reporting of results in each specialty/subspecialty of service. If it is not possible to observe, the surveyor asks for a verbal walk-through of the procedure. Do not distract staff when observing operations and personnel activities.

Focus observations on:

- o Specimen integrity;
- o Quality control performance;
- o Skills and knowledge of personnel regarding:
  - Performance of testing;
  - Evaluation of test results;
  - Identification and resolution of problems; and
  - Interactions with supervisory personnel.

At all times respect patient privacy and do not interfere with patient care and confidentiality.

C. Interviews.--Note the personnel performing the pre-analytic, analytic, and post-analytic phases of the testing process. Interview staff to confirm observations and obtain additional information, as necessary. Ask open ended questions, e.g., probes from the guidelines, and wait for answers to each question. If necessary, repeat or restate the response given by the staff to confirm what was said. During the interview of personnel, evaluate their knowledge and skills for performing

tests, identifying problems and the methods for corrective and remedial actions. Interviews should include as many staff members as necessary to form a judgement as to the ability of staff to perform their duties. Handle all staff or individual allegations of problems as complaints. Determine, as best as possible, the validity of the allegations prior to leaving the laboratory. Do not cite services considered deficient by individuals or staff without verification. Conduct a follow-up investigation, if appropriate, of serious allegations that cannot be substantiated during the present survey, e.g., falsified test results or referral of PT specimens to another laboratory for testing.

D. Record Review.--Gather relevant information that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory including records encompassing the time period since the last certification survey. Determine all new tests, new test methods, and new equipment since the prior survey and include as many of these factors as possible when reviewing laboratory records. The amount of records selected and reviewed is not intended to be statistically valid, but rather a representative cross-section of various records. Avoid predictable patterns of gathering information (e.g., same tests or time periods). Do not allow the laboratory to select the records for review. Consider the types of clients and/or facilities that the laboratory serves, e.g., nursing homes, pediatric, dialysis units, public health clinics, cancer clinics, and routine physicals. Choose a variety of patient records across the laboratory's spectrum of clients. When test information must be gathered from medical records, be considerate when handling these records, as they contain confidential information. If possible, review medical records in the presence of office or laboratory personnel and with consideration to confidentiality.

Review a cross-section of information selected from records of QA. The QA portion of the regulations in 42 CFR Part 493, Subpart P, delineates the laboratory's responsibility for performing its own internal reviews. This is an excellent starting point for an outcome-oriented survey. Review a cross-section of information simultaneously assessing the laboratory's ability to provide quality test results as well as its ability to identify and correct problems. Refer to the QA portion of the regulations as a guide for organizing your selection and review of information to assess the laboratory's overall compliance with the requirement of PT, patient test management, QC, and personnel. Investigate further any test areas identified as a problem but not addressed by the laboratory's QA program. If the laboratory is failing to monitor (or effectively monitor) its own systems and correct its problems, you can direct the laboratory to the requirements and the relevant sections for its particular setting.

Assure that reviews of PT, QC, personnel, and patient test management include the following:

1. PT.--Verify the laboratory is appropriately enrolled and participates in a HCFA approved PT program(s) for each specialty, subspecialty, analyte, and/or test for which the laboratory performs testing.

If the laboratory has unacceptable analyte/test results or unsatisfactory performance in specialties or subspecialties since the last survey, review the specific record, corrective action, and any other data such as education and training of staff associated with PT remediation. Include patient test results which were assayed in the same run as the failed PT in the review. In addition:

- o Verify that the laboratory has reported results under the appropriate methodology/instrumentation used for test performance, e.g., automated vs. manual hematology;

- o Verify the laboratory's records of in-house testing of PT sample with test results reported to the PT program;

- o Verify that PT samples were handled, to the extent practical, in the same manner as patient samples; and

- o Determine for tests where there is no PT available, that the laboratory verifies the accuracy of that test at least twice a year.

2. QC.--Review QC practices and evaluate whether the laboratory is following its own QC protocols or those procedures specified by the manufacturer. Review QC results, including outliers, shifts and trends, and corrective actions taken, when necessary.

Correlate reported patient test data with QC data and/or QA records to ensure proper performance and documentation of controls performed on the day of testing. Review original test data (instrument printouts or computer files). Verify that patient results have not been reported when QC data was unacceptable according to the laboratory's protocol.

Consider the following:

- o Paying particular attention to new methodologies and equipment;
- o QC and calibration materials used;
- o Source and availability of QC limits; and
- o Evaluation and monitoring of QC data.

3. Personnel.--The scope of the review of personnel records (qualifications, training, and competency) will be related to the type of survey, type of testing performed, and the observations and findings of the survey. For initial CLIA certification surveys, evaluate the qualifications of each laboratory director, technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, and cytotechnologist. Evaluate the qualifications of a cross-section of testing personnel.

For CLIA recertification surveys, it is not necessary to review personnel records of individuals previously evaluated unless there have been changes in the individual's position since the last survey. Focus on each new laboratory director, technical consultant, technical supervisor, clinical consultant, general and cytology supervisor, and cytotechnologist. Refer to Subpart M of Appendix C for additional information concerning personnel training, experiences, competency, and qualifications.

4. Patient Test Management.--Using the patient test requisitions, test results, and test reports or, as applicable, patient charts, review all phases of the laboratory=s testing processes, including instructions for specimen storage. If possible, when reviewing individual patient test results, correlate test requisition(s) or medical record information with final report(s). Refer to Subpart P of Appendix C for guidance in reviewing and correlating patient test results. Consider:

- o Reviewing a cross-section of patient test results encompassing all specialties and subspecialties of testing performed in the laboratory in sufficient numbers to determine if results vary significantly from expected population norms;
- o The patient population serviced by the laboratory, e.g., geriatrics, public health clinics, dialysis units, health fairs, and hospitals, when reviewing test results;
- o Examining worksheets or instrument printouts, looking for outliers, trends, etc., when tests are performed in batches;
- o Reviewing several worksheets, instrument printouts, or medical records over time for tests performed at random; and
- o Closely scrutinizing test results that are disproportionately abnormal or normal.

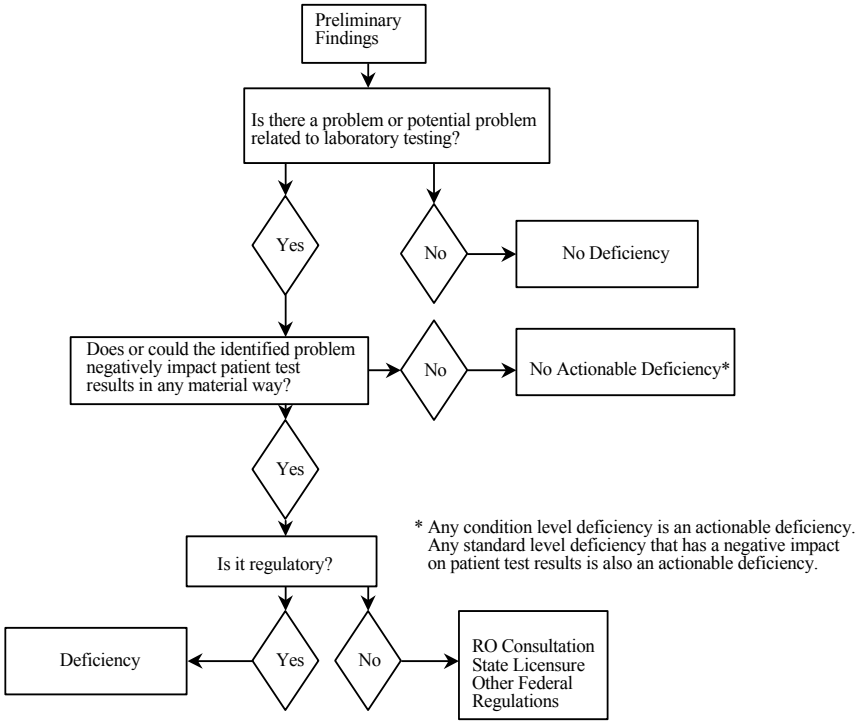
IV. ASSESSING OUTCOME OR POTENTIAL OUTCOME

If the information gathered indicates that the laboratory has established, implemented, and maintained appropriate ongoing mechanisms for monitoring, evaluating, and resolving any problems in its practices, and your findings do not warrant a more in-depth review, conclude the survey. However, if you cannot make an assessment of the laboratory's performance based on the cross-section of information you collected, it may be necessary to expand the cross-section (e.g., number of sites, observations, or number of records). If your findings reveal potential problem areas with any test procedures, ensure the review is sufficient in breadth and depth to substantiate whether a negative or potentially negative outcome exists. If a problem or potential problem related to patient test results is found, determine the nature and seriousness of the problem.

The survey process allows the freedom to increase or decrease the number and types of records reviewed, the personnel interviewed, and the observations made as individual needs are identified.

Analyze your findings for the degree of severity, survey history, frequency of occurrence, impact on delivery of services, i.e., accuracy, reliability, and timeliness of test results. One occurrence of a deficiency directly related to a potential adverse impact on patient testing may be cited. On the other hand, some preliminary findings may have so slight an impact on outcome that they do not warrant ea citation.

Refer to the following chart in assessing outcome. Refer to the next section for guidance in determining regulatory compliance.



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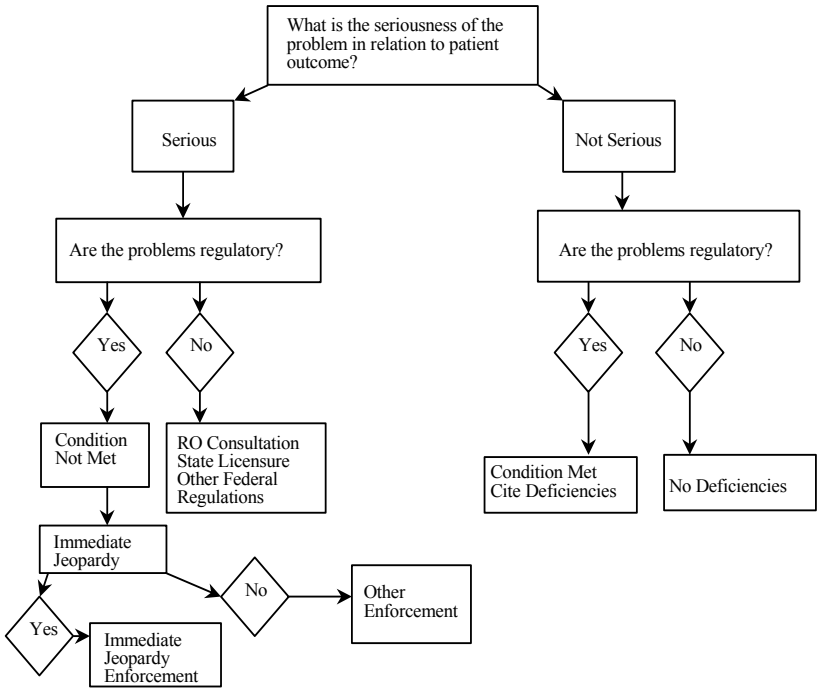
V. REGULATORY COMPLIANCE DECISION

After all necessary information has been collected and the outcome or potential outcome has been evaluated to determine if a preliminary finding constitutes a deficiency, determine if it is a condition level deficiency. Review the findings and decide if additional information and/or documentation is necessary to substantiate a deficient practice.

The number of deficiencies does not necessarily relate to whether or not a condition is found out of compliance, but rather its impact or potential impact on the quality of laboratory services and the results reported. Consider a condition out of compliance for one or more deficiencies if, in your judgment, the deficiency(ies) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care.

o. Determining Immediate Jeopardy.--Immediate jeopardy is defined in 42 CFR §493.2 as "a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health." (See 42 CFR, Subpart R, Enforcement Procedures.) Refer to the following chart for guidance in determining regulatory compliance.



- o What is the seriousness of the problem in relation to patient outcome?
  - Does the problem result in inaccurate test results?
  - Does the problem result in a high probability of inaccurate test results?
  - Is the situation one in which immediate corrective action is necessary because the laboratory's noncompliance has already caused or is likely to cause serious injury, harm, or death to individuals served by the laboratory or to the health or safety of the general public?
- o What are the regulatory considerations?
  - Are regulatory deficiencies identified?
  - Do the deficiencies pose an immediate jeopardy to patient health and welfare?
  - Do the deficiencies warrant removal of a certificate?
  - Is there an option for other enforcement remedies?

VI. EXIT CONFERENCE

The purpose of the exit conference is to review your findings with the laboratory and is not meant to be all inclusive. It is the continuation of the educational survey process and the beginning of due process where laboratories have the first opportunity to present additional information in response to the findings.

If immediate jeopardy or condition-level deficiencies are identified, inform the laboratory of the scope of the problem(s)/finding(s) and indicate that they are not final and are subject to review. Consider the following when conducting an exit conference:

- o Conduct the exit conference with the facility's administrator, director, consultant, or supervisor, and/or other invited staff;
- o Describe the requirements that are not in compliance and the findings that substantiate these deficiencies;
- o Provide the laboratory an opportunity to discuss and provide additional information regarding deficiencies. It is the laboratory's responsibility to determine the corrective action(s) necessary to remedy the problem(s);
- o Provide instructions and the time frame necessary for submitting a plan of correction as referenced in Chapter 6, §6130;
- o Refer to Chapter 6, §6126 for additional information on the exit conference including the presence of counsel, taping of the exit conference, and situations that would justify refusal to conduct or continue an exit conference. If a tape is made of the exit conference, get a copy before you leave;
- o Inform the facility of your intended recommendation to the RO to certify, recertify, or deny certification of the laboratory; and
- o At the exit interview, inform the laboratory (director/administrator/supervisor) of changes in test volumes which may result in fee changes.

The appropriate representative of the laboratory (i.e., laboratory director or designee) should initial the changed total volume on Form HCFA-116 (CLIA application) or Form HCFA-1557 (laboratory survey report) as written attestation to the accuracy of the information supplied.

VII. DEVELOPMENT OF THE STATEMENT OF DEFICIENCIES

Choose the most appropriate regulatory citation when documenting a deficiency. Since the outcome-oriented survey process begins with your review of the laboratory's QA program (for its completeness and incorporation into the day-to-day operations of the laboratory), the status of the QA program will be instrumental when deciding where to cite deficiencies. If deficient practices are a result of failure of the laboratory to properly monitor an area, cite the deficiency in the QA area. If deficient practices are more basic or systemic, such as failure of the laboratory to perform or perform correctly certain tasks or requirements, then cite the deficiency in the specific area of the regulation such as personnel, QC, or patient test management. Supporting information for documenting deficiencies should be complete, clear, and concise. Write the deficiency statement in terms which allow a reasonably knowledgeable person to understand the aspects of the requirements that are not met. Avoid writing the same deficiency in several places. Write your statement of evidence following the format described in the Principles of Documentation.

For any cited deficiency in patient test management, general QC, and QA, Automated Survey Processing Environment (ASPEN) will request that you list the appropriate specialty or subspecialty identifier code(s) for each D-tag. Use the list provided on Form HCFA-1557 that identifies the code number for each specialty and subspecialty (e.g., hematology § 400). This is applicable to standard and condition-level deficiencies.

A. Conditions Out of Compliance in Patient Test Management, Personnel, or QA.--If you have determined that deficiencies exist within the condition(s) of patient test management, personnel, and/or QA that are significant and have potential for, or adversely affect patient testing, cite the most appropriate condition not met.

B. General QC vs. Specialties/Subspecialties.--The QC regulations are established according to moderate and high complexity testing. 42 CFR 493.1202 separates the QC requirements of moderate and high complexity testing as follows:

- 42 CFR 493.1202(a) lists the requirements for all high complexity tests;

- 42 CFR 493.1202(b) lists the requirements for moderate complexity tests that have been modified or are not approved through a Food and Drug Administration (FDA) process (i.e., the QC requirements for high complexity testing apply while the requirements for personnel are moderate); and

- 42 CFR 493.1202(c) lists the requirements for all non-modified moderate complexity tests approved by the FDA.

The areas provided in §1202(a) and (b) do not have D-tags and cannot be used for citing deficiencies. Deficiencies can be cited at the tagged areas under §1202(c) for moderate complexity testing.

The following indicates the regulatory approach to citing QC deficiencies. First review the D-tags under the appropriate specialty/subspecialty. If an appropriate tag is not available in the specialty/subspecialty area, use an appropriate D-tag in general QC. See below for guidance.

Specialty or Subspecialty
QC 42 CFR 493.1223-1285
D-tags D4188-4512

General QC
Moderate (non-modified) Complexity Testing
42 CFR 493.1202(c)(1-7)
D-tags 4001-4006 & 4173-4181

General QC
High Complexity/
Moderate/In-House
42 CFR 493.1204-1221
D-tags 4012-4185

C. Citing Condition-Level Deficiencies in QC.--Review the condition statements at the general QC section of the regulation and at each specialty and subspecialty. Each statement includes the requirements that must be met for that particular condition to be met.

o General QC - The laboratory must meet the requirements at 42 CFR 493.1202-1221.

o Specialties/Subspecialties - The laboratory must meet the requirements of each specialty/subspecialty (ex. Hematology, 42 CFR 493.1253) in addition to any applicable parts of general QC. (42 CFR 493.1202-1221).

NOTE: General QC includes only those requirements at 42 CFR 493.1202-1221, but the conditions at the specialties and subspecialties include both the requirements in the specific specialty or subspecialty and those of general QC.

When a standard level deficiency(ies) is of a serious nature, and you determine that the condition is out of compliance, write the condition-level deficiency at the particular specialty or subspecialty using the format shown in the Principles of Documentation.

Use general QC only when the deficient practice(s) is pervasive throughout the laboratory and correction is necessary for testing to continue in any specialty or subspecialty of the laboratory. As stated in the Principles of Documentation, the deficiencies that are determined to cause a condition to be out of compliance must all be corrected before the condition can be marked back in compliance. When citing the condition of general QC out of compliance, ASPEN will request the specialty and/or subspecialty identifying code(s) and whether the condition is for moderate complexity testing, high complexity testing or both. The identifying specialty/subspecialty codes can be found on Form HCFA-1557 (e.g., routine chemistry - 310).

EXAMPLE - A laboratory has deficiencies in bacteriology under D-tags at the bacteriology specialty location (42 CFR 493.1223) as well as in general QC [42 CFR 493.1202(c)(1) (7)] and chemistry deficiencies under D-tags in general QC [42 CFR 493.1202(c)(1) (7)7]. The surveyor determines that the deficiencies in both areas constitute condition-level noncompliance. The surveyor must write the condition of bacteriology out of compliance (42 CFR 493.1227) based on the deficiencies cited in the bacteriology specialty area (42 CFR 493.1227) and the D-tags in general QC at [42 CFR 493.1202(c)(1)(7)]. The surveyor must write the condition of chemistry out of compliance based on chemistry deficiencies cited in the general QC area [42 CFR 493.1202(c)1-7]. Even though the D-tags used to determine the condition-level noncompliance in chemistry are cited in general QC, the appropriate condition to mark out of compliance is the applicable subspecialty of chemistry (42 CFR 493.1245, 1247, 1249 or 1251).

Since the condition of general QC includes only those requirements at 42 CFR 493.1202-1221, citing the condition of general QC out of compliance for this example would require the laboratory to correct only those deficiencies cited in general QC (in this example part of the bacteriology deficiencies and all of the chemistry deficiencies). When the two specialty conditions are marked out of compliance, the laboratory can choose to correct one specialty without the other and the SA can recommend an adverse action to limit the certificate for the one specialty that has been corrected. If the surveyor had cited the condition of general QC out of compliance using the deficiencies in the example, and the laboratory had only corrected one of the specialty areas, the adverse action would have to be taken against the entire certificate (laboratory) and not just the specialty. Use the condition of general QC only when the deficiencies are pervasive throughout the laboratory and correction must be made for the laboratory to continue testing in any specialty. One example of appropriate use of the condition of general quality control would be a laboratory lacking electricity necessary for all areas of testing offered.

VIII. SURVEY REPORT DOCUMENTATION AND DATA ENTRY

Following each survey, as applicable, complete the following additional documentation. This information remains in the official file, either at the SA or RO. Also include Forms HCFA-209 and HCFA-1513 (completed by the laboratory) in the official file.

As applicable, complete the following:

Form HCFA-1557, Survey Report Form (CLIA);

Form HCFA-462A/B, CLIA Adverse Action Extract;

Form HCFA-2567, Statement of Deficiencies and Plan of Correction;

Form HCFA-2567B, Post Certification Revisit Report;

Form HCFA-1539, Certification and Transmittal;

Form HCFA-670, Survey Team Composition and Workload Report;

Form HCFA-282, Blood Bank Inspection Checklist and Report; and

Form HCFA-562, Medicare/Medicaid/CLIA Complaint Form.

Following the survey, enter into the CLIA/OSCAR/ODIE data system(s) any revisions, additions, or deletions to the application (Form HCFA-116) information. Refer to the CLIA Systems Users Guide for specific information and instruction. Enter into the ODIE data system the Certification Kit, which consists of:

Form HCFA-1539, Certification and Transmittal;

Form HCFA-1557, Survey Report Form (CLIA) - pages 1 and 2;

Form HCFA-2567, Statement of Deficiencies and Plan of Correction; and

Form HCFA-670, Survey Team Composition and Workload Report.

Enter into the CLIA/OSCAR data system, when applicable:

Form HCFA-462A/B, CLIA Adverse Action Extract; and

Form HCFA-562, Medicare/Medicaid/CLIA Complaint Form.

IX. ADDITIONAL INFORMATION

COUNTING TESTS

Total annual volume for waived tests, if any, should be recorded on the CLIA application (Form HCFA-116) in the waived testing section. The total annual volume for nonwaived tests, including PPM procedures, should be reported on the form in the Nonwaived Testing section by specialty and subspecialty. Only tests that are ordered and reported should be included in the laboratory's test volume(s). Calculations (e.g., A/G ratio, MCH, MCHC, HCT, and T7), QC, QA, and PT assays should not be counted.

- For chemistry tests, each non-calculated analyte is counted separately (e.g., SMA-18 profile equals 18 tests).

- For complete blood counts, each measured individual analyte that is ordered and reported is counted separately. Differentials count as one test.

- For urinalysis, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

- For microbiology, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.

- Testing for allergens should be counted as one test per individual allergen.

- For gynecologic and nongynecologic cytology, each slide (not case) is counted as one test.

- For immunohematology each ABO, Rh, antibody screen, cross match, or antibody identification is counted as one test.

- For histocompatibility, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test.

- For histopathology, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

- For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient (i.e., a bone marrow and a venous blood specimen received on one patient are counted as two tests).

CONDUCTING SURVEYS OF PARTIALLY ACCREDITED SPECIALTIES/SUBSPECIALTIES

A laboratory that has certain specialties/subspecialties that are certified by HCFA and other specialties that are accredited by an approved accrediting organization is considered a partially accredited laboratory. During the course of a survey of the HCFA-certified specialties, a finding in an accredited specialty may be observed. Contact the RO to ascertain whether such onsite findings are to be investigated as a complaint or validation survey before initiating an evaluation of the finding(s) observed. The determination as to whether the finding(s) would be investigated as a complaint or a validation survey may depend on when the accrediting organization conducted a survey. Refer to Chapter 6 for specific policy and instructions related to surveys for complaint and/or validation investigations.

CONDUCTING SURVEYS OF MULTIPLE TESTING SITES UNDER ONE CERTIFICATE

A. As specified in 42 CFR Part 493, all not-for-profit or State or local government laboratories engaged in limited public health testing and certified under a single certificate must meet all applicable requirements of 42 CFR Part 493. Each location is subject to a survey, although not every location may be included in the cross-section of information gathered during the current certification survey period. If there is a central or primary location, include it in the initial CLIA certification survey. Select a representative portion of the remaining locations for onsite survey.

Select sites for the survey based on:

- Types of testing performed;
- Types of clients and/or facilities served, e.g., pediatric, geriatric, residential/emergency care, or health assessment screens;
- Location(s) participating in PT; and
- Problems or complaints identified either at the central or primary location, or other testing sites.

B. In a hospital, laboratory testing sites under one certificate should be inspected using the criteria listed above.

C. Temporary testing sites, including mobile units, should be inspected using the criteria listed in A above. Refer to the '6034 to assist with determining what constitutes a mobile unit. Every effort should be made to schedule the survey to coincide with testing at temporary locations.

Many Home Health Agencies (HHAs) may have fallen under the exception contained in the CLIA regulations for not-for-profit or government entities involved in limited public health testing. HHAs may also fall under the CLIA certification exception for laboratories with temporary testing locations. Refer to Transmittal Number 98-1 (Program Memorandum, State Survey Agencies) to assist with determining (on a case-by-case basis) whether or not a Medicare HHA actually qualifies to have multiple testing sites under a single CLIA certificate.

A laboratory having multiple sites under one certificate is required to enroll in only one PT program(s) for each specialty/subspecialty/analyte tested under that certificate even though the same analyte may be tested at multiple locations using different test systems, methodologies, or personnel.
Assure that PT records indicate the location at which the tests were performed, and that all other locations have been compared with the system selected for PT, as specified in 42 CFR 493.1709.

A condition may be considered out of compliance for deficiencies found at <u>one</u> or more locations.

CONDUCTING SURVEYS OF WAIVED TESTS

In any laboratory holding a CLIA certificate, waived tests are not subject to routine survey. A survey of waived tests may be conducted only when authorized by the RO:

- o To collect information on waived tests;
- o If a complaint is alleged; or
- o If you have information that the performance of such tests poses a situation of immediate jeopardy.

CONDUCTING SURVEYS OF CERTIFICATE FOR PPM PROCEDURES

If a laboratory holds a Certificate for PPM procedures, do not conduct a certification or recertification survey of these facilities. However, a survey may be conducted as specified in 42 CFR Part 493, Subpart Q (i.e., randomly to determine whether the laboratory is performing tests in addition to those listed as PPM procedures or waived tests, to collect information regarding the appropriateness of tests specified as PPM, to determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to the public, and to investigate complaints). When performing a survey of PPM procedures, the appropriate requirements in 42 CFR Part 493 Subparts H, J, K, M, P and Q apply.

NEXT PAGE IS C-23.1

D-TAG CROSSWALK

Page #	OLD TAG	NEW TAG	OTHER ACTION
C-62	D2001	-	Incorporated text under D2000
C-63	D2002	D2001	New tag
C-63	D2003	D2002	New tag
C-63	D2004	D2003	New tag, revised reg text (HSQ-202)
C-63	D2005	D2004	New tag
C-64	D2006	D2005	New tag
C-64	-	D2006	New tag
C-65	D2013	D2013	Revised reg text (HSQ-202), expanded tag
C-67	D2017	D2017	Revised reg text (HSQ-202)
C-87	-	D2141	New tag
C-87	D2141	D2142	New tag
C-87	D2142	D2143	New tag
C-87	D2143	D2144	New tag
C-88	D2144	D2145	New tag
C-88	D2145	D2146	New tag
C-88	D2146	D2147	New tag
C-88	D2147	D2148	New tag
C-88	D2148	D2149	New tag
C-88	D2149	D2150	New tag
C-88	D2150	D2151	New tag
C-88	D2151	-	Deleted tag, revised reg text (HSQ-202)
C-96	-	D3014	New tag (HSQ-202)
C-97	D3018	D3018	Revised reg text (HSQ-202)
C-98	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-99	D3036	D3035	New tag, revised reg text (HSQ-202)
C-99	-	D3036	New tag
C-99	-	-	Corrected D-tag cross-reference in surveyor guidelines

Page #	OLD TAG	NEW TAG	OTHER ACTION
C-100	D3048	D3048	Revised reg text (HSQ-202)
C-103	D3077	D3077	Added text from D3078
C-103	D3078	-	Deleted tag
C-104	D4000	D4000	Revised reg text (HSQ-202)
C-107	D4003	D4003	Revised reg text (HSQ-202)
C-110	D4018	D4018	Revised reg text (HSQ-202)
C-113	D4040	D4040	Revised tag
C-113	D4041	D4041	Revised tag
C-123	D4105	D4105	Revised reg text (HSQ-202)
C-127	-	D4142	New tag
C-131	-	D4178	New tag
C-141	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-155	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-162	-	D4295	New tag (HSQ-202)
C-162	D4298	-	Moved to p. C-164
C-163	D4300	D4298	Reversed tag (HSQ-202)
C-164	-	D4300	Reversed tag from p. C-162, revised reg text (HSQ-202)
C-164	D4302	D4302	Revised reg text (HSQ-202)
C-166	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-167	D4318	D4318	Revised reg text (HSQ-202)
C-167	D4319	D4319	Revised reg text (HSQ-202)
C-167	D4320	D4320	Revised reg text (HSQ-202)
C-168	D4321	D4321	Revised reg text (HSQ-202)
C-170	D4338	-	Deleted tag
C-170	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-172	D4350	D4350	Revised reg text (HSQ-202)
C-172	-	-	Corrected D-tag cross-reference in surveyor guidelines

Page #	OLD TAG	NEW TAG	OTHER ACTION
C-179	D4425	D4425	Added text from D4426
C-180	D4426	-	Deleted tag
C-183	D4442	D4440	New tag
C-183	D4443	D4442	New tag
C-183	D4444	D4443	New tag
C-183	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-184	-	D4444	New tag, revised reg text (HSQ-202)
C-192	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-194	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-195	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-196	D4481	-	Deleted tag, added text to D4480
C-196	D4484	D4484	Revised reg text (HSQ-202)
C-205	D6004	D6004	Added (a) and (b) to tag
C-216	D6065	D6065	Added (3) and (4) to tag
C-222	D6079	D6079	Added (a) and (b) to tag
C-226	D6110	-	Deleted tag, added text to D6109
C-248	D6120	D6120	Added (8) to tag
C-250	D6130	D6130	Added (3) to tag
C-250	D6131	D6131	New tag for (4)
C-252	D6143	D6143	Added 1st sentence of (b)
C-254.1	D6147	D6147	Revised reg text (HSQ-202)
C-254.1	D6151	D6151	Added (4) to tag
C-255	D6152	D6152	Revised reg text (HSQ-202)
C-262.1	D6180	-	Deleted tag, added text to D6179
C-263	D6182	D6182	Revised reg text (HSQ-202)
C-263	-	D6183	New tag (HSQ-202)
C-266	D7034	-	Deleted tag, added text to D7033
C-267	D7043	D7043	Revised reg text (HSQ-202)

Page #	OLD TAG	NEW TAG	OTHER ACTION
C-267	D7047	D7047	Revised reg text (HSQ-202)
C-268	D7058	D7058	Revised reg text (HSQ-202)
C-269	D7067	D7067	Revised reg text (HSQ-202)
C-270	D8000	D8000	Revised reg text (HSQ-202)
C-270.1	D8010	-	Deleted tag
C-270.1	-	D8044	New tag (HSQ-202)
C-270.2	-	D8045	New tag (HSQ-202)
C-270.2	-	D8046	New tag (HSQ-202)
C-270.2	-	D8047	New tag (HSQ-202)
C-270.2	-	D8048	New tag (HSQ-202)
C-271	-	D8049	New tag (HSQ-202)
C-271	-	D8050	New tag (HSQ-202)
C-271	-	D8051	New tag (HSQ-202)
C-271	-	D8052	New tag (HSQ-202)
C-271	-	D8053	New tag (HSQ-202)
C-271	-	D8011	New tag
C-272	-	-	Corrected D-tag cross-reference in surveyor guidelines
C-273	D8025	-	Deleted tag
C-273	D8026	-	Deleted tag
C-273	D8027	D8027	Revised reg text (HSQ-202)
C-275	D8040	D8039	New tag, revised reg text (HSQ-202)
C-275	D8043	-	Deleted tag
C-275	-	-	Corrected D-tag cross-reference in surveyor guidelines

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Subpart A - General Provisions **§493.1 Basis and scope.** This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.	
	§493.2 Definitions. As used in this part-- Accredited institution means a school or program which-- (a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate; (b) Is legally authorized within the State to provide a program of education beyond secondary education; (c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;	§493.2(d) Guidelines: An accrediting agency approved by the Secretary means a school or program which is approved by: (1) The Council of Medical Education of the American Medical Association (AMA); (2) One of the six regional accreditation programs listed in the latest edition of Education Directory, Colleges and Universities, printed by HHS Education Division (New England Association of Schools and Colleges, Southern Association of Colleges and Schools, Northwest Association of Schools and Colleges, North Central Association of Colleges and Schools, Middle States Association of Colleges and Secondary Schools, and Western Association of Schools and Colleges); (3) New York Board of Regents, Albany, New York; or (4) National Association of Trade and Technical Schools, Accrediting Commission, 2021 L Street, N.W., Washington, D.C. 20036. Schools approved by any of these agencies or associations are listed in the Education Directory referred to above. AMA schools are also listed in the Allied Medical Education Directory which may be obtained from the AMA order department, 535 North Dearborn, Chicago, Illinois 60610. The annual guide issue of the Journal of the American Hospital Association also lists these schools. In administering this section of the regulations, it must be understood that individuals qualify by completing their training in an accredited school at a time when the school is accredited. If there is any question about the accreditation status of the school, contact the accrediting agency involved. If there is an issue concerning the confirming of a particular degree by an institution, contact the school involved for a decision.

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	(d) Is accredited by a nationally recognized accrediting agency or association. This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.	Equivalency evaluations for foreign academic credentials will be performed by any organization that is a member of the National Association of Credential Evaluations Services, Inc. (NACES). The following are members of NACES as of the publication of these guidelines: Center for Applied Research, Evaluation & Education, Inc. P.O. Box 20348 Long Beach, CA90801 Phone: 213-430-1105 Educational Credential Evaluators, Inc. P.O. Box 17499 Milwaukee, WI53217-0499 Phone: 414-964-0477 Fax: 414-964-8291 Education Evaluators International, Inc. P.O. Box 5397 Los Alamitos, CA90721 Phone: 213-431-2187 Fax: 213-493-5021 Education International 29 Denton Road Wellesley, MA02181 Phone: 617-235-7425 Fax: 617-235-6831 Foreign Academic Credentials Service, Inc. P.O. Box 367 Glen Carbon, IL62034 Phone: 618-288-5892 Foundation for International Services, Inc. 3123 Eastlake Avenue East Seattle, WA98102-3875 Phone: 206-328-0260 Fax: 206-726-0528 International Consultants of Delaware, Inc. 109 Barksdale Prof. Center Newark, DE19711 Phone: 302-737-8715 Fax: 302-737-8756 International Education Research Foundation, Inc. P.O. Box 66940 Los Angeles, CA90066 Phone: 213-390-6276 Fax: 213-397-7686 Josef Silny & Associates International Educational Consultants P.O. Box 248233 Coral Gables, FL33124 Phone: 305-596-4580 World Education Services, Inc. P.O. Box 745 New York, NY10113-0745 Phone: 212-966-6311 Fax: 212-966-6395
	Analyte means a substance or constituent for which the laboratory conducts testing.	
	Authorized person means an individual authorized under State law to order tests or receive test results, or both.	
	Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.	
	CLIA means the Clinical Laboratory Improvement Amendments of 1988.	
	CLIA certificate means any of the following types of certificates issued by HCFA or its agent: (1) Certificate means a certificate issued to a laboratory after an inspection that finds the laboratory in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with §493.630, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements. (2) Certificate for physician-performed microscopy procedures means a certificate issued or reissued, pending an appeal, in accordance with §463.630, to a	

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	laboratory in which a physician performs only the microscopy tests listed in §493.16(b), or issued or reissued to a laboratory in which a physician performs microscopy tests and waived tests as listed in §493.15(c). (3) Certificate of accreditation means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA, (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.632, when a validation or complaint survey has found the labortory to be noncompliant with one or more CLIA conditions. (4) Certificate of registration or registration certificate means a certificate issued or reissued, pending an appeal, in accordance with §493.626, to an entity that is not qualified to receive a certificate of waiver or certificate for physician-performed microscopy procedures, that enables the entity to conduct moderate or high complexity laboratory testing until the entity is determined to be in compliance through a survey by HCFA, its agent, or the State; is accredited by an approved accreditation organization; or becomes exempt from CLIA by virtue of it being licensed by a State with a HCFA-approved laboratory licensure program.	

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	(5) Certificate of waiver means a certificate issued or reissued, pending an appeal, in accordance with §493.631, to a laboratory to perform only the waived tests listed at §493.15(c).	
	CLIA-exempt laboratory means a licensed laboratory in a State whose licensure program is approved by HCFA and is exempt from CLIA requirements (i.e., State-exempt).	
	HHS means the Department of Health and Human Services, or its designee.	
	Kit means all components of a test that are packaged together.	Currently, in-vivo and externally attached patient dedicated monitoring devices, e.g., as pulse oximetry, SvO2 pulmonary artery catheters, capnographs, are not subject to CLIA. Should it be determined at a later date that they are subject to CLIA, proper notice and opportunity for public comment will be provided. Tissue embedding, sectioning, and staining in Pathology are considered part of specimen preparation, not a laboratory test, and do not fall under CLIA. Macroscopic (gross) examinations of specimens must be performed by an individual qualified under §493.1449(l)(1). However, the laboratory that interprets histopathology and oral pathology slide preparations must ensure that a control slide is included with each slide or group of slides for differential or special stains as required under §§493.1258 and 493.1261. Also, laboratories that screen or interpret cytopathology slides are responsible for ensuring that cytology slides are stained and/or prepared in compliance with applicable requirements at §§493.1218(f)(2) and 493.1258(a)(1)-(4).
	Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.	

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	Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.	
	Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.	
	Physician means an individual with a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine, or equivalent degree who is licensed by the State to practice medicine or podiatry.	
	Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.	
	Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).	

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	Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.	
	Target Value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.	
	Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.	

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	Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.	
	§493.3 Applicability.	
	(a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it-- (1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, a certificate, or a certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or (2) Is CLIA-exempt.	§493.3(b) Guidelines: The purpose for which the test is conducted, not the test itself, determines whether a facility conducting testing is subject to the CLIA requirements. Testing that is used to gather evidence for legal purposes, and is not performed for purposes of clinical treatment, medical diagnosis, health assessment or disease prevention is not subject to CLIA. For blood donor screening, the FDA requirements are product-related, while CLIA requirements are donor/recipient-related. Tests such as hepatitis, HIV and syphilis serology, among others, are used in donor screening to assess the health of the person donating blood, one of the activities that come within the statutory definition of "laboratory". Therefore, the performance of these tests must meet CLIA requirements. Industrial laboratories that monitor employee health and test for drugs of abuse, insurance company laboratories that assess an individual's health for insurance purposes, health maintenance organizations, and other facilities such as pharmacies and health fairs that perform screening test procedures are also subject to CLIA requirements. Individuals who self-administer a test in their own home with a device that has been cleared specifically for home use by the FDA are not regulated under CLIA. To the extent that a home health agency (HHA) or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, by virtue of that activity, CLIA requirements for the HHA or hospice do not apply. However, an HHA or hospice that performs laboratory testing on individuals that meets the definition for laboratory testing in §493.2 is subject to CLIA requirements.
	(b) Exception. These rules do not apply to components or functions of-- (1) Any facility or component of a facility that only performs testing for forensic purposes; (2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or (3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.	

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	(c) Federal laboratories. Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.	§493.3(c) Guidelines: Refer to §6015 of the State Operations Manual (SOM) to assist in distinguishing which laboratories are under the jurisdiction of the Federal government for purposes of inspecting for CLIA.
	§493.10 Categories of tests by complexity.	
	(a) Laboratory tests are categorized as either-- (1) Waived tests; (2) Tests of moderate complexity; or (3) or Tests of high complexity. (b) A laboratory may perform only waived tests, only tests of moderate complexity, only tests of high complexity or any combination.	
	(c) Each laboratory must be either CLIA-exempt or possess one of the following, as defined in this part: (1) Registration certificate; (2) Certificate of waiver; (3) Certificate; or (4) Certificate of accreditation.	
	§493.15 Laboratories performing waived tests.	
	(a) Requirement. Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.	
	(b) Criteria. Test systems are simple laboratory examinations and procedures which-- (1) Are cleared by FDA for home use; (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or	

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	(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.	
D1000	(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests--visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate -non-automated; (6) Hemoglobin - copper sulfate - non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.	§493.15(c) Guidelines: Cite D1000 on the HCFA-2567 and solicit a Plan of Correction when a laboratory has failed to obtain a registration certificate before performing and reporting patient results for tests not listed in §493.15. Notify the RO of a possible action by the OIG if the laboratory does not obtain the appropriate certificate or cease non-waived testing.

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	(d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.	
D1001	(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and	§493.15(e) Guidelines: Tests listed on the waiver list in §493.15(c) are not subject to routine survey. A survey of waived tests may be conducted only when authorized by the RO in the following instances: o To collect information on waived tests; o If a complaint is alleged; or o You have information that the performance of such tests poses a situation of immediate jeopardy. Refer to §493.1775 for additional guidelines for inspecting laboratories issued a certificate of waiver.
	(2) Meet the requirements in Subpart B, Certificate of Waiver, of this part.	
	§493.16 Physician-performed microscopy procedures.	
	(a) Requirement. Procedures to be categorized as physician-performed microscopy procedures must meet the criteria specified in paragraph (b) of this section.	
	(b) Criteria. Procedures must meet the following specifications: (1) The examination must be personally performed by a physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member; (2) The procedure must be categorized as moderately comples; (3) The primary instrument for performing the test is the microscope;	

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	(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result; (5) Control materials are not available to monitor the entire testing process; and (6) Limited specimen handling or processing is required.	
	(c) Physician performed microscopy examinations. A laboratory may qualify to perform tests under this provision if it restricts physician-performed microscopy examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others; (1) Wet mounts, including preparation of vaginal, cervical or skin specimens; (2) All potassium hydroxide (KOH) preparations; (3) Pinworm examinations; (4) Fern tests; (5) Post-coital direct, qualitative examinations of vaginal or cervical mucous; and (6) Urine sediment examinations.	
	(d) Revisions to criteria and the list of physician-performed microscopy procedures. (1) The Clinical Laboratory Improvement Advisory Committee (CLIAC) will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of procedures. (2) HHS will determine whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a physician-performed microscopy	

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	procedure. Revisions to the list of physician-performed microscopy procedures proposed by HHS will be published in the **Federal Register** as a Notice with an opportunity for public comment.	
	(e) Laboratories eligible for test performance under the physician-performed microscopy examination provision must- (1) Meet the applicable requirements in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, subpart F, general administration, or if applicable, subpart D, certificate of accreditation, subpart H, participation in proficiency testing, subpart J, patient test management, subpart K, quality control, and subpart P, quality assurance, of this part. (2) In lieu of the requirements contained in subpart M, personnel, meet the following requirements: (i) The laboratory must have a director who- (A) Possesses a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; (B) Is a doctor of medicine, doctor of osteopathy, or doctor of podiatry licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (C) Is responsible for ensuring that any procedure listed in paragraph (c) of this section is- (1) Personally performed by a physician on a specimen from his	

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	or her own patient or from a patient of a group medical practice of which the physician is a member; and (2) Performed in accordance with the applicable requirements to subparts H, J, K, and P or this part. (ii) Any procedure listed under paragraph (c) of this section must be personally performed by a phyxician during the patient visit on a specimen from his or her own patient or from a patient of group medical practice of which the physician is a member. (3) Be subject to inspection only under the circumstances specified under §493.1776 but are not routinely inspected to determine compliance with the requirements specified in paragraphs (e)(1) and (2) of this section.	
	§493.17 Test categorization.	
	(a) Categorization by criteria. Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while	

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	those receiving scores above 12 will be categorized as high complexity. **NOTE:** A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3". (1) Knowledge. (i) Score 1. (A) Minimal scientific and technical knowledge is required to perform the test; and (B) Knowledge required to perform the test may be obtained through on-the-job instruction. (ii) Score 3. (A) Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing. (2) Training and experience. (i) Score 1. (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and (B) Limited experience is required to perform the test. (ii) Score 3. (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or (B) Substantial experience may be necessary for analytic test performance. (3) Reagents and materials preparation. (i) Score 1. (A) Reagents and materials are generally stable and reliable; and (B) Reagents and materials are prepackaged, or premeasured, or	

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	require no special handling, precautions or storage conditions. (ii) Score 3. (A) Reagents and materials may be labile and may require special handling to assure reliability; or (B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements. (4) Characteristics of operational steps. (i) Score l. Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled. (ii) Score 3. Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations. (5) Calibration, quality control, and proficiency testing materials. (1) Score 1. (A) Calibration materials are stable and readily available; (B) Quality control materials are stable and readily available; and (C) External proficiency testing materials, when available, are stable. (2) Score 3. (A) Calibration materials, if available, may be labile; (B) Quality control materials may be labile, or not available; or (C) External proficiency testing materials, if available, may be labile.	

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	(6) Test system troubleshooting and equipment maintenance. (i) Score l. (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and (B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed. (ii) Score 3. (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or (B) Maintenance requires special knowledge, skills, and abilities. (7) Interpretation and judgment. (i) Score 1. (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and (B) Resolution of problems requires limited independent interpretation and judgment; and (ii) Score 3. (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and (B) Resolution of problems requires extensive interpretation and judgment.	
	(b) Revisions to the criteria for categorization. The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.	

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	(c) Process for device/test categorization utilizing the scoring system under §493.17(a). (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations: (A) When categorizing previously uncategorized new technology; (B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and (C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75. (ii) Test categorization will be effective as of the notification to the applicant. (2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.	§493.17©(11) Guideline: If a test is categorized between publications of the FEDERAL RESGISTER listings, the Laboratory should maintain a copy of the letter from the FDA (to the manufacture) Indicating the test complexity.

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	(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year. (4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant. (5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.	§493.20 Guidelines: See §6010 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.
	§493.20 Laboratories performing tests of moderate complexity.	
	(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to certificate of waiver tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity.	
	(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C, registration certificate and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality	

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	control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections, of this part. For physician-performed microscopy procedures, the personnel requirements contained in §493.16(e)(2) are applicable in lieu of subpart M of this part and inspections are required only under the circumstances specified in §493.1776.	§493.25 Guidelines: See §6010 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.
	(c) If the laboratory also performs certificate of waiver tests listed in §493.15, compliance with subparts H, J, K, M, P, and Q of this part for routine inspections are not required for the waived tests. However, the laboratory must comply with the requirements in §§493.15(d) and 493.1775.	
	§493.25 Laboratories performing tests of high complexity.	
	(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in §493.17(a).	
	(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C, registration certificate and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections, of this part.	

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	(c) If the laboratory also performs certificate of waiver tests, the requirements of subparts H, J, K, M, P, and Q of this part for routine inspections are not applicable for the waived tests. However, the laboratory must comply with the requirements in §§493.15(e) and 493.1775.	
	(d) If the laboratory also performs tests of moderate complexity, the personnel requirements of subpart M are applicable for the performance of tests of moderate complexity as well as Subparts H, J, K, P, and Q of this part.	

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	Subpart B--Certificate of Waiver **§493.35 Application for a certificate of waiver.** (a) Filing of application. Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in §435.15(b) of this chapter must file a separate application for each laboratory location.	§493.35(b)(1) Guidelines: Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed. If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection. Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request. Mobile vans will be distinguished by the vehicle identification number (VIN #). §493.35(b)(2) Guidelines: See §6145 of the SOM for the definition for limited public health testing. See §6145 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application. §493.35(b)(3) Guidelines: "Common direction" means that all testing sites are under one designated director. "Street address" is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.
	(b) Exceptions. (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address. (2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application. (3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.	
	(c) Application format and contents. The application must--(1) Be made to HHS or its designee on a form or forms prescribed by HHS;	

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	(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including-- (i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes; (ii) The methodologies for each laboratory test procedure or examination performed, or both; and (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.	§493.35(d) Guidelines: Cite deficiencies for not following manufacturer's instructions at §493.15(e). (D1001)
	(d) Access requirements. Laboratories that perform one or more waived tests listed in §493.15(c) and no other tests must-- (1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and §493.15(e); (2) Agree to permit unannounced inspections by HHS in accordance with subpart Q of this part-- (i) When HHS has substantive reason to believe that the laboratory is being operated in a	§493.35(d)(2)(i) Guidelines: Consult with your RO for assistance in determining when there is substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health. An example of a substantive reason to inspect waived testing is if testing personnel are observed cutting urine dipsticks in half. (This violates both the manufacturer's instructions and causes questionable results to be reported.)

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	manner that constitutes an imminent and serious risk to human health; (ii) To evaluate complaints from the public; (iii) On a random basis to determine whether the laboratory is performing tests not listed in §493.15; and (iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §493.15.	§493.35(d)(2)(ii)-(iii) Guidelines: See §6280 of the SOM for specific procedures regarding complaint investigations and §6210 of the SOM for random surveys.
	(e) Denial of application. If HHS determines that the application for a certificate of waiver is to be denied, HHS will-- (1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part; (2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and (3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.	
	§493.37 Requirements for a certificate of waiver.	
	(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of §493.35.	
	(b) Laboratories issued a certificate of waiver-- (1) Are subject to the requirements of this subpart and §493.15(e) of subpart A of this part; and	§493.37(b)(1) Guidelines: Cite the laboratory's failure to follow manufacturer's instructions at §493.15(e). (Use D1001.)

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	(2) Must permit unannounced inspections by HHS in accordance with subpart Q of this part.	§493.37(d) Guidelines: See the Adverse Action section of the SOM beginning at §6300 for enforcement procedures.
	(c) Laboratories must remit the certificate of waiver fee specified in Subpart F of this part.	
	(d) In accordance with Subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with Subpart R of this part.	
	(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part. (2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.	

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	(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.	
	(f) A laboratory seeking to renew its certificate of waiver must-- (1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and (2) Meet the requirements of §§493.35 and 493.37.	
	(g) A laboratory with a certificate of waiver that wishes to perform examinations or test procedures not listed in the waiver test category must meet the requirements set forth in subparts C or D of this part.	
	§493.39 Notification requirements for laboratories issued a certificate of waiver.	
	Laboratories performing one or more tests listed in §493.15 and no others must notify HHS or its designee-- (a) Before performing and reporting results for any test or examination that is not specified under §493.15 for which it does not have a registration certificate as required in subparts C or D of this part; and	§§493.39(a)(b) Guidelines: See §6010 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.
	(b) Within 30 days of any change(s) in-- (1) Ownership;	See the section of the SOM regarding Actions Related to Certification beginning at §6100 for instructions on handling changes in ownership, name, location, or director.
	(2) Name;	
	(3) Location; or	
	(4) Director.	

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	Subpart C--Registration Certificate, Certificate for Physician-performed Microscopy Procedures, and Certificate **§493.43 Application for registration certificate, certificate for physician-performed microscopy procedures, and certificate.**	§493.43(b)(1) Guidelines: Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed. If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection. Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request. Records may be maintained in the mobile laboratory or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test. Mobile vans will be distinguished by the vehicle identification number (VIN #). §493.43(b)(2) Guidelines: See §6145 of the SOM for the definition of limited public health testing. See §6145 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application. §493.43(b)(3) Guidelines: In instances where the main laboratory is certified to perform waived, moderate and/or high complexity tests, the alternate sites may perform testing in all complexities covered by the certificate provided that all other applicable requirements are met (e.g., quality control, personnel). "Common direction" means that all sites are under one designated director. "Street address" is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.
	(a) Filing of application. Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate or high complexity, or both, must file a separate application for each laboratory location.	
	(b) Exceptions. (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address. (2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application. (3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.	

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	(c) Application format and contents. The application must-- (1) Be made to HHS or its designee on a form or forms prescribed by HHS; (2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including-- (i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes); (ii) The methodologies for each laboratory test procedure or examination performed, or both; and (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.	
	(d) Access and reporting requirements. All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.	
	§493.45 Requirements for a registration certificate.	§493.45(a) Guidelines: After September 1, 1992, all facilities performing laboratory testing must have a registration certificate or certificate of waiver prior to performing patient testing. See §6010 of the SOM for instructions on handling a laboratory operating without an appropriate CLIA certificate.
	(a) A registration certificate is required-- (1) Initially for all laboratories performing test procedures of moderate and high complexity	

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	(Exception: For physician-performed microscopy procedures listed in §493.16(c), the laboratory is not issued a registration certificate but is subject to §§493.43 and 493.47 and must apply and obtain a certificate for physician-performed microscopy procedures prior to conducting the procedures listed in §493.16(c)); (2) For all certificate of waiver laboratories that intend to perform testing in addition to those tests listed in §493.15(c); and (3) For any laboratory that intends to perform testing in addition to physician-performed microscopy procedures listed in §493.16(c) and waived procedures listed in §493.15(c). (b) HHS will issue a registration certificate if the laboratory-- (1) Complies with the requirements of §493.43; (2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only); (3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and (4) Remits the fee for the registration certificate, as specified in subpart F of this part.	
	(c) Prior to the expiration of the registration certificate, a laboratory must- (1) Remit the certificate fee specified in subpart F of this part;	

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	(2) Be inspected by HHS as specified in subpart Q of this part; and (3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.	
	(d) In accordance with subpart R, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.	
	(e) A registration certificate is-(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and (2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.	
	(f) In the event of a non-compliance determination resulting in an HHS denial of a laboratory's certificate application, HHS will provide the laboratory with a statement of grounds on which the non-compliance determination is based and offer an opportunity for appeal as provided in subpart R.	§493.45(f) Guidelines: See the Appeals section of the SOM beginning at §6450 for instructions on denial of a certificate application.
	(g) If the laboratory requests a hearing within the time specified by HHS, it retains its	

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	registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.	
	(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.	
	§493.47 Requirements for a certificate for physician-performed microscopy procedures.	
	(a) A certificate for physician-performed microscopy procedures is required-- (1) Initially for all laboratories performing test procedures listed in §493.16(c); and (2) For all certificate of waiver laboratories that intend to perform only test procedures listed in §493.16(c) in addition to those tests listed in §493.15(c).	
	(b) HHS will issue a certificate for physician-performed microscopy procedures if the laboratory-- (1) Complies with the requirements of §493.43; and (2) Remits the fee for the certificate, as specified in subpart F or this part.	
	(c) Laboratories issued a certificate for physician-performed microscopy procedures are subject to--	

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	(1) The notification requirements of §493.53; (2) The applicable requirements of this subpart and subparts H, J, K, and P or this part. In lieu of the requirements contained in subpart M of this part, for physician-performed microscopy procedures, the laboratory must meet the requirements of §493.16(e)(2); and (3) Inspection only under the circumstances specified under §493.1776, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c)(1) and (2) of this section.	
	(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for physician-performed microscopy procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.	
	(e) A certificate for physician-performed microscopy procedures is valid for a period of no more than 2 years.	
	§493.49 Requirements for a certificate.	
	(a) HHS will issue a certificate to a laboratory only if the laboratory-- (1) Meets the requirements of §§493.43 and 493.45 (§493.45 is	

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	not applicable to physician-performed microscopy procedures); (2) Remits the certificate fee specified in Subpart F of this part; and (3) Meets the applicable requirements of this subpart and subparts H, J, K, M (not applicable to physician-performed microscopy procedures), P, and Q of this part. In lieu of the personnel requirements contained in subpart M, for physician-performed microscopy procedures, the laboratory must meet the requirements of §493.16(e)(2).	
	(b) Laboratories issued a certificate-- (1) Are subject to the notification requirements of §493.51; and (2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q (provision for conducting inspections of the physician-performed microscopy procedures listed in §493.16(c) is located at §493.1776) of this part-- (i) To determine compliance with the requirements of this part. Exception: In accordance with §493.16(e)(3), inspections of physician-performed microscopy procedures are not routinely conducted); (ii) To evaluate complaints; (iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and (iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §§493.15 and 493.16 or	

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	tests of moderate or high complexity.	
	(c) Failure to comply with the requirements of this subpart will result in-- (1) Suspension, revocation or limitation of a laboratory's certificate in accordance with subpart R of this part; and (2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.	
	(d) A certificate issued under this subpart is valid for no more than 2 years.	
	(e) In the event of a non-compliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate, HHS will-- (1) Provide the laboratory with a statement of grounds on which the determination of non-compliance is based; and (2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate or reissued certificate until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when criteria at §493.1840(a)(4) and (5) are met.	
	(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance	

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	determination even if there has been no appeals decision issued.	
	(g) A laboratory seeking to renew its certificate must-- (1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate; and (2) Meet the requirements of §493.43 and paragraphs (a)(2) and (b)(2) of this section.	
	(h) If HHS determines that the application for the renewal of a certificate is to be denied or limited, HHS will notify the laboratory in writing of the-- (1) Basis for denial of the application; and (2) Opportunity for appeal as provided in subpart R.	§493.49(h) Guideline: See the Appeals section of the SOM beginning at §6450 for instructions on denial of a certificate application.
	(i) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate or reissued certificate until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.	
	(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate even if there has been no appeals decision issued.	
	§493.51 Notification requirements for laboratories issued a certificate.	§493.51 Guidelines: See the section of the SOM regarding Actions Related to Certification beginning at §6135 and §3215 for handling changes in ownership, name, location, personnel and test methodology, or additions or deletions of specialties or subspecialties that may result in changes in complexity levels for the laboratory.
	Laboratories issued a certificate must: (a) Notify HHS or its designee within 30 days of any change in--	See the Adverse Action section of the SOM beginning at §6300 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.

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	(1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity testing only).	
	(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate, so that compliance with requirements can be determined; and	
	(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate.	
	§493.53 Notification requirements for laboratories issued a certificate for physician-performed microscopy.	
	Laboratories issued a certificate for physician-performed microscopy procedures must notify HHS or its designee--	
	(a) Before performing and reporting results for any test or examination that is not specified under §§493.15 and 493.16(c) for which it does not have a registration certificate as required in subparts C or D of this part; and	
	(b) Within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; or (4) Director.	

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	Subpart D--Certificate of Accreditation **§493.55 Application for registration certificate and certificate of accreditation.** (a) Filing of application. A laboratory performing one or more tests of moderate complexity or high complexity, or both may be issued a certificate of accreditation in lieu of a certificate provided the laboratory-- (1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and (2) Files a separate application for each location, except as specified in paragraph (b) of this section.	§493.55(a)(1) Guideline: When HHS approves accreditation organizations and State licensure programs, the ROs are notified and the approved organizations and programs are published as a notice in the Federal Register. See the section of the SOM for special procedures for accredited laboratories and CLIA-exempt laboratories beginning at §6600. §493.55(b)(1) Guidelines: Laboratories with multiple testing sites or mobile laboratories eligible for a single certificate should obtain a separate certificate for each State in which testing is performed. If a mobile laboratory operates in more than one State and does not obtain a separate certificate from each State, contact the RO to determine which State conducts the inspection. Each laboratory that moves from testing site to testing site, or has a temporary testing location, should provide the survey agency with the home base or central dispatch phone number so that an updated schedule of the location of testing and the hours of operation can be obtained upon request. Records may be maintained in the mobile laboratory or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test. Mobile vans will be distinguished by the vehicle identification number (VIN #). §493.55(b)(2) Guidelines: See §6145 of the SOM for the definition of limited public health testing. See §6145 of the SOM for assistance in determining whether laboratories under the same ownership can file a single application.
	(b) Exceptions. (1) Laboratories that are not at a fixed location, that is laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address. (2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.	

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	(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.	§493.55(b)(3) Guidelines: "Common direction" means that all sites are under one designated director. "Street address" is the address assigned by the Post Office and is the physical location of the laboratory. The street address may be different from the mailing address, which can be a Post Office box or a billing address. For large hospitals, such as a university campus facility, that may contain laboratories in separate buildings, consult with the RO to determine if the hospital is eligible for a single certificate.
	(c) Application format and contents. The application must-- (1) Be made to HHS on a form or forms prescribed by HHS; (2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the Public Health Service Act; and (3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including-- (i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes); (ii) The methodologies for each laboratory test procedure or examination performed, or both; and (iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.	
	(d) Access and reporting requirements. All laboratories must make records available and	

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	submit reports to HHS as HHS may reasonably require to determine compliance with this section.	§493.57 Guidelines: See §6010 of the SOM for instructions on handling a laboratory operating without a CLIA certificate.
	§493.57 Requirements for a registration certificate.	
	A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate issued by HHS.	
	(a) HHS will issue a registration certificate if the laboratory-- (1) Complies with the requirements of §493.55; (2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only); (3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and (4) Remits the fee for the registration certificate specified in subpart F of this part.	
	(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program-(i) Within 11 months of issuance of the registration certificate; or (ii) Prior to the expiration of the certificate. (2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of subpart C, §493.49 of this part.	
	(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or	

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	limitation of a laboratory's registration certificate and will deny the laboratory's applicationfor a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.	§493.57(e) Guideline: See the Appeals section of the SOM beginning at §6450 for instructions on denial of a certificate of accreditation application.
	(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in §493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.	
	(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will-- (1) Deny a laboratory's request for certificate of accreditation; (2) Notify the laboratory if it must meet the requirements for a certificate as defined in Subpart C of this part; (3) Provide the laboratory with a statement of grounds on which the application denial is based; (4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS	

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	finds that conditions at the laboratory pose an imminent and serious risk to human health; and (5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.	
	§493.61 Requirements for a certificate of accreditation.	
	(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory-- (1) Meets the requirements of §493.57 or, if applicable, §493.49 of subpart C of this part; and (2) Remits the certificate of accreditation fee specified in subpart F of this part.	
	(b) Laboratories issued a certificate of accreditation must-(1) Treat proficiency testing samples in the same manner as patient samples; (2) Meet the requirements of §493.63; (3) Comply with the requirements of the approved accreditation program; (4) Permit random sample validation and complaint inspections as required in subpart Q of this part; (5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section; (6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and	§493.61(b)(5) Guideline: See the section of the SOM regarding Special Procedures for Accredited and CLIA-exempt laboratories beginning at §6600 for procedures on follow-up of correction of deficiencies cited during validation inspections.

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	(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.	§493.61(d) Guidelines: 42 CFR §488.11 refers to State survey agency functions.
	(c) A laboratory failing to meet the requirements of this section-(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program; (2) Will be subject to full determination of compliance by HHS; (3) May be subject to suspension revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and (4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.	
	(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with §488.11 of this chapter.	
	(e) Failure to meet the applicable requirements of Part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will-- (1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; (2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and	

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	(3) Offer an opportunity for appeal as provided in subpart R of this part.	
	(f) If the laboratory requests a hearing within the time frame specified by HHS-- (1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and (2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.	
	(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or §493.57.	§493.61(g) Guideline: Accrediting organizations which lose deemed status are required to notify their participating laboratories. These laboratories must apply for a CLIA certificate.
	(h) A laboratory seeking to renew its certificate of accreditation must-- (1) Complete and return the renewal application to HHS 9 to l2 months prior to the expiration of the certificate of accreditation; (2) Meet the requirements of this subpart; and (3) Submit the certificate of accreditation fee specified in subpart F of this part.	
	(i) If HHS determines that the renewal application for a certificate of accreditation is to	

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	be denied or limited, HHS will notify the laboratory in writing of-- (1) The basis for denial of the application; (2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part; (3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and (4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs. **§493.63 Notification requirements for laboratories issued a certificate of accreditation.**	
	Laboratories issued a certificate of accreditation must: (a) Notify HHS and the approved accreditation program within 30 days of any changes in -- (1) Ownership;	§493.63 Guideline: See the section of the SOM regarding Actions Related to Certification beginning at §§6135 and 6215 of the SOM for handling changes in ownership, name, location, personnel and additions or deletions of specialties or subspecialties. See the Adverse Action section of the SOM beginning at §6300 for instructions on handling laboratories that are going out of business or voluntarily withdrawing from all testing.
	(2) Name;	
	(3) Location; or	
	(4) Director.	

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	(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.	
	(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.	

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	Subpart H--Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both	The implementation of proficiency testing (PT) requirements will be staggered, that is, phased into effect. The factor that determines when a laboratory will be held to PT requirements is its regulatory history. For phase-in purposes, all laboratories are divided into one of two groups. Previously regulated laboratories, i.e., laboratories that were subject to the March 14, 1990, regulation, constitute the first group. These are independent laboratories (including physician offices that received any specimens on referral), non-accredited hospitals and laboratories formerly regulated under CLIA '67 (those accepting specimens in interstate commerce). All remaining laboratories constitute the second group, and are referred to as "previously unregulated laboratories." The phase-in will be accomplished in two steps: Previously Regulated Laboratories: 1. - Previously regulated laboratories will, beginning September 1, 1992, be held to all PT requirements except §493.803, Successful participation. 2. - Successful PT performance will be applicable in 1994. Previously Unregulated Laboratories: 1. - Previously unregulated laboratories will, beginning January 1, 1994, be held to all PT requirements except §493.803, Successful participation. 2. - Successful PT performance will be applicable in 1995. Subpart H - Guidelines - General PT programs are evaluated initially for HHS approval and annually thereafter for re-approval. After review and affirmative recommendations from the Centers for Disease Control (CDC), Central Office (CO) will issue PT program approvals and/or re-approvals. A listing of these programs with the specialties, subspecialties, and analytes for which they are approved will be provided to ROs prior to and for the next calendar year. The RO is responsible for disseminating the approved program listing to the States within their region on an annual basis. Address questions related to the currently approved PT programs to the RO. An approved PT program is a program that has been evaluated and found to be in compliance with the requirements of Subpart I. When a laboratory experiences problems with PT, it resolves them with the PT program. If a PT program fails to meet the requirements of Subpart I, report all available information to the RO, which discusses the findings with CO. CO, with CDC recommendations, renders a decision on the termination or continued approval of the PT program, as appropriate.

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D2000	**§493.801 Condition: Enrollment and testing of samples.**	§493.801 Guidelines: For each laboratory, determine the extent of patient testing services performed by the laboratory. Verify that the laboratory has enrolled in an approved program(s) for those required specialties, subspecialties, and analytes as described in Subpart I (listed below in the respective specialty) in which it performs testing on patient specimens. PT requirements apply to moderate and high complexity tests listed in Subpart I. PT is not required for waived tests. If a laboratory enrolls and participates in PT for any waived tests, do not review these PT results and do not determine compliance with any other PT requirements. PT enrollment and participation is required, as applicable, for each certificate other than a Certificate of Waiver. A facility offering testing at more than one site, but the testing is all included under one certificate, must enroll in an approved PT program(s) for the collective tests covered under that certificate, not for each site. Facilities that perform laboratory testing at multiple sites and are certified under one CLIA certificate include the following examples: o A hospital with satellite laboratories throughout the hospital; o Different departments of the laboratory; o A hospital that performs point-of-care testing; o Limited public health testing performed by non-profit or Federal, State or local government laboratories; or o Mobile laboratories or temporary testing sites. The following examples give instruction and guidance for determining compliance with the PT requirement for enrollment where a specialty, subspecialty or analyte is performed by different methods, specimen types and locations: o A laboratory with a single certificate must enroll in an approved PT program for each analyte listed in Subpart I that it performs. When an analyte is performed using different methodologies within the laboratory, enrollment is required only in one program for the laboratory's primary method. Other methods for the same analyte must be evaluated as required in §493.1709. If the laboratory performs unsuccessfully for an analyte and sanctions are imposed, the sanctions are applicable to the analyte, not to the test methodology. For example, if a laboratory uses three different methods to perform cholesterol measurements, it must participate in PT using the primary method. If the laboratory is unsuccessful in PT performance for cholesterol and the CLIA certificate is suspended, limited, or revoked for cholesterol, the laboratory would be precluded from performing cholesterol by any test method. o A laboratory with a single certificate performing testing at multiple sites under that certificate must participate in PT for each analyte under that certificate listed in Subpart I. PT testing must be performed using the primary method, regardless of the site. If the laboratory uses the primary method at more than one
	Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients'	
	For laboratories subject to 42 CFR Part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.	

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		testing site, the performance of PT testing events may be alternated between different sites, provided the primary method is used to perform the PT. Should the facility not perform successfully for an analyte, that analyte may not be tested at <u>any location</u> under that certificate. o A multiple site laboratory, which is covered by a single certificate and participates in one PT program per analyte, must be aware that a failure in PT could lead to the revocation of its certificate for <u>all</u> sites, not just the one participating in PT. When problems occur that cannot be resolved with the instructions in these guidelines, gather all information available and consult with the RO for guidance and resolution.
	(a)Standard; Enrollment. The laboratory must -	<u>§493.801(a) Guidelines:</u> Enrollment Requirements Effective Dates Previously Regulated Laboratories — Beginning 9/1/92 (for 1993 calendar year) Previously Unregulated Laboratories — 1/1/94 During the on-site survey, verify that the laboratory is enrolled in an approved program or programs, as appropriate, for all specialties, subspecialties, and tests or analytes for which it performs patient testing.
D2001	(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.	
D2002	(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and	To meet the requirements of this section, it may be necessary for a laboratory to enroll in more than one program to cover all tests listed in Subpart I for which the laboratory performs testing. The approved program in which a laboratory has enrolled may not offer every analyte that the laboratory performs. The laboratory must then enroll in an additional program(s) to cover the testing not included in the first program.
D2003	(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1709.	
D2004	(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify HCFA before any change in designation; and	The laboratory must indicate to the PT program which specialty, subspecialty, or analyte it intends the program to grade and score for regulatory purposes. This is particularly necessary when the laboratory subscribes to multiple PT programs that contain the same analyte(s) required for regulatory purposes. <u>§493.801(a)(3) Guidelines:</u> When a laboratory initially applies for CLIA certification or adds a specialty or subspecialty after initial PT enrollment for the calendar year, it may change PT programs at the next PT enrollment period.

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D2005	(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.	§493.801(a)(4) Guidelines: Provide laboratories with the appropriate Federal or State Agency address to which PT results must be sent. §§493.801(a)-(b) Probes: What procedure or test method was used? Is this a routine test method used in the laboratory? Did routine personnel perform the PT? How often were PT samples tested? How are deviations (if any) justified? Do the PT results documented in the laboratory work records (worksheet) correlate with the results reported to the PT program? What is the laboratory's policy for testing patient samples when PT specimens are tested more than once? Do reports submitted to the PT program provider accurately reflect the procedure (i.e., instrument, method) used in the laboratory? Check to see if patient samples were reported on the same day that PT samples were tested. (In a small facility, infrequent testing may necessitate the testing of PT samples without patient specimens to ensure that the the PT test results are returned on time.) Did the laboratory use the same procedure for both patient specimens and PT samples?
	(b) Standard; Testing of proficiency testing samples.	
D2006	The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.	
D2007	(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.	
D2008	The individual testing or examining the samples and	
D2009	the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.	

§493.801(b) Guidelines	Testing of Proficiency Testing Samples Requirement - Effective Dates
Previously Regulated Laboratories	9/1/92
Previously Unregulated Laboratories	1/1/94

Some previously unregulated laboratories may enroll in a PT program prior to the required date of enrollment (1/1/94). A review of these scores would only be for your information and the laboratory cannot be held to any PT requirement under Subpart H before the effective date of the regulation.

Review testing records to determine if special handling was given to PT samples. Consider the unique requirements of many PT samples when evaluating "same manner" of testing. The laboratory should document any necessary reconstitution, longer mixing times, unit conversion of results, etc., as required in §493.801(b)(5).

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D2010	(2) The laboratory must test samples the same number of times that it routinely tests patient samples.	A central laboratory with more than one instrument or methodology for the same test may alternate methods or instruments from one testing event to the next as long as both are routinely used to test patient specimens. All samples for one analyte within a shipment must be tested with the same instrument.
D2011	(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.	§493.801(b)(1) Guidelines: Review records to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)((4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447.
D2012	Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.	
D2013	(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples.	§493.801(b)(4) Guidelines: The regulation refers to intentional referral of PT specimens by a laboratory for purposes of using another laboratory's results as its own. A laboratory that routinely performs only presumptive testing or screening methods and refers patient samples to another laboratory for definitive or confirmatory testing or comparison of test results must not refer PT samples to another laboratory for confirmatory testing. A laboratory must only test and report PT specimens to the extent or degree those tests or examinations are performed for in-house patient testing. Handle allegations of inter-laboratory communications or referral of proficiency testing specimens as a complaint and investigate using the complaint investigation procedures outlined in §6280 of the SOM. **Do not solicit a Plan of Correction from a laboratory when it has been determined that the laboratory intentionally referred its PT samples to another laboratory for analysis and submitted the other laboratory's results as its own. Immediately notify the RO recommending revocation of the certificate and forward to the RO all documentation necessary to support the findings.**

<table>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>D2014</td><td>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.</td><td rowspan="3">§493.801(b)(5) Guidelines:
Review recores to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447. The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.</td></tr>
<tr><td>D2015</td><td>The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</td></tr>
<tr><td></td><td>(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</td></tr>
<tr><td>D2016</td><td>§493.803 Condition: Successful participation.
(a) Each laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.</td><td>§493.803 Guidelines:

<table>
<tr><th></th><th>Successful Participation Requirement - Effective Dates</th></tr>
<tr><td>Previously Regulated Laboratories</td><td>1/1/94</td></tr>
<tr><td>Previously Unregulated Laboratories</td><td>1/1/95</td></tr>
</table>
A laboratory seeking reevaluation of a PT score is to contact the PT program directly. Do not alter or change any unsatisfactory score reported by an approved PT program except when the PT program does not score for the correct extent of services provided. (See §493.823 Guidelines.)</td></tr>
</table>

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(b) If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in subpart R of this part.	"**Unsatisfactory performance**" for a specialty, subspecialty, or analyte or test is defined as one of the following: o Unacceptable (unsatisfactory) analyte score; o Unsatisfactory PT event or overall score for a subspecialty or specialty; o Failure to participate in a testing event; or o Failure to return PT results within the timeframe specified by the approved PT program. "**Unsuccessful participation**" is defined as one of the following: o Unsatisfactory performance for the same analyte or test in two or two out of three consecutive testing events; or o Unsatisfactory performance of a PT testing event or overall score for a specialty or subspecialty in two or two out of three consecutive testing events. **Unless instructed by the RO, do not solicit a Plan of Correction from the laboratory for unsuccessful PT performance.** Example: A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are §§493.825(b), 493.825(e), and 493.803. Example: A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory scores 40% on the same analyte. The citations are §§493.841(a), 493.841(f), and 493.803. When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.
D2017	**§493.807 Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully.** (a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily	

<table>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td></td><td>withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.
(b) The termination period for Medicare or Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation, or suspension of the CLIA certificate.</td><td rowspan="3"></td></tr>
<tr><td>D2018</td><td>(c) If a laboratory's certificate is suspended and/or Medicare or Medicaid approval is terminated in gynecologic cytology, the laboratory must take corrective action and reapply for certification.</td></tr>
<tr><td></td><td>Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate or High Complexity, or Both</td></tr>
<tr><td>D2019</td><td>§493.821 Condition: Microbiology.
The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.</td><td>§493.821 Guidelines:

Successful Participation for Microbiology (Including its Subspecialties) Effective Dates

Previously Regulated Laboratories — 1/1/94

Previously Unregulated Laboratories — 1/1/95</td></tr>
</table>

INTERPRETIVE GUIDELINES - LABORATORIES		
TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.823 Standard; Bacteriology.	
D2020	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2021	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2022	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2023	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2024	(3) The laboratory participated in the previous two proficiency testing events.	
D2025	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2026	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2027	(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2028	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.825 Standard; Mycobacteriology.	
D2029	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2030	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2031	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2032	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2033	(3) The laboratory participated in the previous two proficiency testing events.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2034	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2035	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2036	(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2037	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.827 Standard; Mycology.	
D2038	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2039	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2040	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2041	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2042	(3) The laboratory participated in the previous two proficiency testing events.	
D2043	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2044	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2045	(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2046	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.829 Standard; Parasitology.	
D2047	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2048	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2049	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2050	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2051	(3) The laboratory participated in the previous two proficiency testing events.	
D2052	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2053	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2054	(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2055	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.831 Standard; Virology.	
D2056	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2057	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2058	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2059	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2060	(3) The laboratory participated in the previous two proficiency testing events.	
D2061	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2062	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2063	(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2064	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2065	**§493.833 Condition: Diagnostic immunology.** The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.	§493.833 Guidelines: Successful Participation for Diagnostic Immunology Effective Dates Previously Regulated Laboratories: 1/1/94 Previously Unregulated Laboratories: 1/1/95
	§493.835 Standard; Syphilis serology.	
D2066	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2067	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
	Consideration may be given to those laboratories failing to participate in a testing event only if--	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2068	(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2069	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2070	(3) The laboratory participated in the previous two proficiency testing events.	
D2071	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2072	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2073	(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2074	(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.837 Standard; General immunology.	Analytes or tests for which laboratory PT performance is to be evaluated: **Diagnostic Immunology** General immunology Alpha-I antitrypsin Alpha-fetoprotein (tumor marker) Antinuclear antibody Antistreptolysin O - quantitative Anti-human immunodeficiency virus (HIV) Complement C3 Complement C4 Hepatitis markers (HBsAg, anti-HBc, HBeAg) IgA IgG IgE IgM Infectious mononucleosis Rheumatoid factor Rubella
D2075	(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.	
D2076	(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2077	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2078	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2079	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2080	(3) The laboratory participated in the previous two proficiency testing events.	
D2081	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2082	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2083	(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2084	(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2085	(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2086	**§493.839 Condition: Chemistry.** The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.	§493.839 Guidelines: Successful Participation for Chemistry Effective Dates Previously Regulated Laboratories — 1/1/94 Previously Unregulated Laboratories — 1/1/95

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.841 Standard; Routine chemistry.	Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma or blood samples: **Chemistry** Routine chemistry Alanine aminotransferase (ALT/SGPT) Albumin Alkaline phosphatase Amylase Aspartate aminotransferase (AST/SGOT) Bilirubin, total Blood gas (pH, pO_2, and pCO_2) Calcium, total Chloride Cholesterol, total Cholesterol, high density lipoprotein Creatine kinase Creatine kinase isoenzymes Creatinine Glucose (Excluding measurements on devices cleared by FDA specifically for home use) Iron, total Lactate dehydrogenase (LDH) LDH isoenzymes Magnesium Potassium Sodium Total Protein Triglycerides Urea Nitrogen Uric Acid
D2087	(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.	
D2088	(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2089	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2090	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2091	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2092	(3) The laboratory participated in the previous two proficiency testing events.	
D2093	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2094	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2095	(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2096	(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2097	(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.843 Standard; Endocrinology.	Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, blood, or urine: **Chemistry** Endocrinology Cortisol Free Thyroxine Human Chorionic Gonadotropin (Excluding color comparison tests for urine specimens) T_3 Uptake Triiodothyronine Thyroid-stimulating hormone Thyroxine
D2098	(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.	
D2099	(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2100	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2101	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2102	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2103	(3) The laboratory participated in the previous two proficiency testing events.	
D2104	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2105	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2106	(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2107	(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2108	(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.845 Standard; Toxicology.	Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, or blood: **Chemistry** **Toxicology** **Alcohol (blood)** **Blood lead** **Carbamazepine** **Digoxin** **Ethosuximide** **Gentamicin** **Lithium** **Phenobarbital** **Phenytoin** **Primidone** **Procainamide (and metabolite)** **Quinidine** **Theophylline** **Tobramycin** **Valproic Acid**
D2109	(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.	
D2110	(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2111	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2112	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2113	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2114	(3) The laboratory participated in the previous two proficiency testing events.	
D2115	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2116	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2117	(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2118	(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2119	(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2120	**§493.849 Condition: Hematology.** The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.	§493.849 Guidelines: Successful Participation for Hematology Effective Dates Previously Regulated Laboratories 1/1/94 Previously Unregulated Laboratories 1/1/95
	§493.851 Standard; Hematology.	
D2121	(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.	Analytes or tests for which laboratory PT performance is to be evaluated: **Hematology** Cell identification or white blood cell differential Erythrocyte count Hematocrit (excluding spun microhematocrit) Hemoglobin Leukocyte count Platelet count Fibrinogen Partial thromboplastin time Prothrombin time
D2122	(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2123	(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2124	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2125	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2126	(3) The laboratory participated in the previous two proficiency testing events.	
D2127	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2128	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2129	(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2130	(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing ventsis unsuccessful performance.	
D2131	(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2132	**§493.853 Condition: Pathology.** The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.	§493.855 Guidelines PT enrollment requirements for gynecologic smear examination will not become effective until 1/1/94.
	§493.855 Standard; Cytology: gynecologic examinations. To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.	
D2133	(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1994.(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1994.	
D2134	The laboratory must ensure that each individual is tested at least once per year and	
D2135	obtains a passing score.	
	To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section .	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2136	(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in §493.945.	
D2137	Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section.	
D2138	Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section.	
D2139	Individuals are given not more than 2 hours to complete a 10-slide test and	
D2140	Not more than 4 hours to complete a 20-slide test.	
D2141	Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.	
D2142	(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set.	
D2143	For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.	
D2144	(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set.	

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D2145	For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and	
D2146	must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent.	
D2147	Reexamination of slides must be documented.	
D2148	(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set.	
D2149	An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and	
D2150	may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and	
D2151	until he or she is retested with a 20-slide test set and scores at least 90 percent.	
	(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, HCFA will initiate intermediate sanctions or limit the	

<table>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td></td><td>laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.</td><td></td></tr>
<tr><td>D2152</td><td>§493.857 Condition: Immunohematology. The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.</td><td rowspan="8">§493.857 Guidelines:

Successful Participation for Immunohematology Effective Dates

Previously Regulated Laboratories — 1/1/94

Previously Unregulated Laboratories2 — 1/1/95

Analytes or tests for which laboratory PT performance is to be evaluated:

Immunohematology
ABO group (excluding subgroups)
D(Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification</td></tr>
<tr><td></td><td>§493.859 Standard; ABO group and D (Rho) typing.</td></tr>
<tr><td>D2153</td><td>(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</td></tr>
<tr><td>D2154</td><td>(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</td></tr>
<tr><td>D2155</td><td>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.</td></tr>
<tr><td>D2156</td><td>Consideration may be given to those laboratories failing to participate in a testing event only if--
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;</td></tr>
<tr><td>D2157</td><td>(2) The laboratory notifies the inspecting agency and the proficiency testing program within</td></tr>
</table>

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2158	(3) The laboratory participated in the previous two proficiency testing events.	
D2159	(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2160	(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2161	(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2162	(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
D2163	(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.861 Standard; Unexpected antibody detection.	
D2164	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2165	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2166	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2167	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2168	(3) The laboratory participated in the previous two proficiency testing events.	
D2169	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2170	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2171	(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2172	(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.863 Standard; Compatibility testing.	
D2173	(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.	
D2174	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
D2175	Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2176	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2177	(3) The laboratory participated in the previous two proficiency testing events.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2178	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2179	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2180	(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2181	(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	
	§493.865 Standard; Antibody identification.	
D2182	(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.	
D2183	(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event.	
	Consideration may be given to those laboratories failing to participate in a testing event only if--	

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D2184	(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;	
D2185	(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and	
D2186	(3) The laboratory participated in the previous two proficiency testing events.	
D2187	(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.	
D2188	(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.	
D2189	(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.	
D2190	(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.	

INTERPRETIVE GUIDELINES - LABORATORIES		
TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D2191	(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.	

<table>
<tr><th colspan="3">INTERPRETIVE GUIDELINES - LABORATORIES</th></tr>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>D3000</td><td>Subpart J - Patient Test Management For Moderate or High Complexity Testing, or Both

§493.1101 Condition: Patient test management; moderate or high complexity testing, or both.
Each laboratory performing moderate or high complexity testing, or both, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards of this subpart as they apply to the testing performed.</td><td rowspan="11">§§493.1103(a)-(c) Probes:
How does the laboratory assure that special handling of specimens is maintained throughout the testing process when necessary, e.g., Micro-GC cultures; Chem-CPK; Endo-Folate/B12; Tox-Carboxyhemoglobin?

What instructions does the laboratory provide to patients when patient preparation is required for optimal specimen collection? For example:
o Semen analysis collection and transportation;
o Fasting instructions for cholesterol fractionation (e.g., HDL, VLDL, LDL);
o Glucose tolerance preparation;
o Twenty-four hour urine collection for specific tests; or
o Fasting and two hour post prandial glucose collections.

What instructions are provided for specimen preservation and transportation, when applicable? For example:
o Sputum for cytology;
o Specimens for renin;
o Specimens for potassium; or
o Specimens for urine culture and colony count.</td></tr>
<tr><td></td><td>§493.1103 Standard; Procedures for specimen submission and handling.</td></tr>
<tr><td></td><td>(a) The laboratory must have available and follow written policies and procedures for each of the following, if applicable:</td></tr>
<tr><td>D3001</td><td>methods used for the preparation of patients;</td></tr>
<tr><td>D3004</td><td>specimen collection;</td></tr>
<tr><td>D3007</td><td>specimen labeling;</td></tr>
<tr><td>D3010</td><td>specimen preservation;</td></tr>
<tr><td>D3013</td><td>conditions for specimen transportation; and</td></tr>
<tr><td>D3014</td><td>specimen processing.</td></tr>
<tr><td></td><td>Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported.</td></tr>
</table>

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D3016	(b) If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) of this section.	Are instructions clearly written and available to all individuals involved in the preservation, transportation, and collection of specimens, e.g., laboratory staff, patients, physicians? When tests are not performed on-site, do instructions for specimen collection, preservation and transportation reflect the specifications of the particular reference laboratory that is receiving the specimen(s)? How do clients obtain additional assistance for specimen handling for unusual circumstances not routinely addressed in a service manual, e.g., the physician did a biopsy and has no 10% buffered formalin and needs to know what substitute is acceptable? If tests are not performed daily, are specimens stored in accordance with the laboratory's procedures to assure specimen integrity? How does the laboratory's specimen identification system assure that each patient's specimen is uniquely identified, e.g., patients with the same names? How does the laboratory handle and label a specimen that is aliquotted for "in-house" testing in multiple areas and for reference laboratory testing, e.g., sputum sent to Mycobacteriology and Cytology, stool specimen for occult blood, routine culture, parasitology and C.difficile toxin assay? Does the laboratory maintain and follow a current client service manual (with specific specimen requirements) pertinent for the reference laboratory performing the test(s)? §493.1105 Guidelines: An "authorized person" means an individual authorized under State law to order tests or receive test results, or both. The patient's chart or medical record, if used as a requisition, must be available to the laboratory at the time of testing, and to HHS upon request, and must be maintained in lieu of a separate form for at least two years. §493.1105 Probes: How does the laboratory maintain records documenting oral requests for testing? How does the laboratory assure that electronic test requests are received from an individual authorized to order such tests? What mechanism does the laboratory employ to request written documentation of oral test requests? If the laboratory attempts to obtain written authorization for oral test requests within 30 days, the requirement is met.
	(c) Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions where applicable.	
	§493.1105 Standard; Test requisition.	
D3017	The laboratory must perform tests only at the written or electronic request of an authorized person.	
D3018	Oral requests for laboratory tests are permitted only if the laboratory subsequently requests written authorization for testing within 30 days. The laboratory must maintain the written authorization or documentation of efforts made to obtain a written authorization.	
D3019	Records of test requisitions or test authorizations must be retained for a minimum of two years.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D3020	The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and must be available to the laboratory at the time of testing and available to HHS upon request.	§§493.1105(a)-(f) Guidelines: If any specimen information other than the patient name or unique identifiers is missing from the test requisition or patient medical record or chart, the laboratory determines whether to test the specimen. Laboratories should either obtain missing information or report results and indicate on the test report, medical record or chart any limitations of test results due to the omission of patient information. However, if the laboratory determines that information is essential to the provision of accurate results, it must be obtained prior to reporting. If the requisition has designated areas for obtaining information, and the laboratory provides instructions to its clients specifying that these items must be completed, the laboratory has demonstrated compliance with the requirement. However, the laboratory must have an ongoing mechanism for monitoring and evaluating the information solicited and obtained on the test requisition. (Use D7009, D7010 and D7019, as appropriate.) Attempts to gain the necessary information must be documented. (Use D7066.) §§493.1105(a)-(f) Probes: How does the laboratory obtain information missing from the requisition form? How does the requisition provide for inclusion of additional information when necessary, e.g., specimen type, source, time collected? When the patient's chart or medical record is used as the test requisition, is it available to the personnel performing laboratory tests at the time of testing or prior to the reporting of test results? Does it provide all the information necessary to ensure accurate testing and reporting of results? §493.1105(b) Guidelines: The address of the individual or laboratory requesting a test should include the street, city or town and the State of the individual or laboratory ordering or responsible for utilizing the test result. When appropriate, a telephone number or other mechanism to contact the responsible individual should be provided to the laboratory. §493.1105(f) Guidelines: Additional information may include the patient's age, sex, current medications, the time the specimen was collected, diagnosis, and the type of specimen to be tested, e.g., serum, urine, spinal fluid.
D3022	The laboratory must assure that the requisition or test authorization includes-- (a) The patient`s name or other unique identifier;	
D3023	(b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;	
D3024	(c) The test(s) to be performed;	
D3025	(d) The date of specimen collection;	
D3026	(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and	
D3029	(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.1107 Standard; Test records.	§493.1107 Guidelines: The regulations provide laboratories the flexibility to establish a system that ensures positive patient identification through specimen accessioning and storage, testing and reporting of test results. This may include a system that involves labeling the specimen container and request slip or the patient's medical record or chart with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the testing and reporting processes. The patient's name may be used as part of the identification system. See the Guidelines at §493.1107(d) for the identification of personnel performing testing. §493.1107 Probes: How does the patient's name or unique identifier used by the system track patient specimens from collection, accessioning, processing and specimen testing through reporting and storage of test results? Do the records reflect all the tests and the dates of performance in patient testing, e.g., in bacteriology, is each test from media inoculation leading to organism isolation and identification documented on worksheet records or in a computer system? Examine work records for handwritten results beside crossed out or whited out printed values. If the handwritten values were reported, can the laboratory demonstrate the analytical source of those results? (Use D3032 or D3050, as appropriate.) Does the laboratory's record system permit easy tracking of a patient test from the request, through the original analytical record to the final report? Are the original analytical work records complete, i.e., in a randomly chosen sample, is there an instrument printout for every day of the month on which testing was performed? Are the original, as opposed to transcribed and/or edited work records, being retained? §493.1107(d) Guideline: The regulations provide laboratories flexibility in establishing a system that identifies personnel performing testing. The system may include signatures, codes, initials, or other identifiers, but must accurately correlate with the identity of the personnel involved in testing. Testing does not include specimen processing (preanalytic) or test reporting (postanalytic) phases of testing. Records may include, but are not limited to, work records, computer systems, or test reports, but must meet record retention requirements as specified in the regulations. §493.1107(d) Probes: How do laboratory records accurately reflect which tests were performed by each individual involved in the testing process? Are high complexity tests performed and supervised, as appropriate, by individuals who meet the qualification requirements for high complexity personnel? (See §§493.1441 - 493.1489.)
D3032	The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported.	
	These records must identify the personnel performing the testing procedure.	
D3034	Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years.	
D3035	Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR Part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).	
D3036	The record system must provide documentation of information specified in §493.1105(a) through (f)	
D3037	and include -- (a) The patient identification number, accession number, or other unique identification of the specimen;	
D3038	(b) The date and	
D3039	time of specimen receipt into the laboratory	
D3040	(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and	
D3041	(d) The records and dates of all specimen testing,	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D3042	including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results.	§493.1109 Guidelines: An "exact duplicate" is an exact copy of the information sent to the individual requesting the test or using the test result(s), and includes the name and address of the laboratory performing the test. The exact copy need not be paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information sent to the individual ordering the test or utilizing the test results. For tests requiring an authorized signature or containing personnel identifiers, the exact duplicate must include the signatures or identifiers, i.e., pathology. "Pathology" includes all of its subspecialties, i.e., histopathology, oral pathology, cytology. The regulations do not require that instrument printouts be posted directly in the patient's medical record or chart. However, these printouts must be maintained as part of the laboratory's record retention requirements specified throughout the regulations. A "preliminary report" means a test result that has been reported to the authorized person or laboratory that initially requested the test before the final test result is completed. Frequently, a preliminary report will contain significant, but not definitive information, e.g., a urine culture preliminary report of >100,000 Gram negative bacilli after 24 hours incubation or a beta subunit preliminary report of >200 miu/ml. It should be noted on the report when the result is a preliminary result with a final report to follow. Preliminary and final reports must contain proper patient identification. Partial reports may be issued by a laboratory when multiple tests are ordered on the same specimen or patient, and partial reports are issued for only those tests which have been completed. Final reports will be issued pending the completion of the remaining tests. The patient's chart or medical record may be used to report test results in lieu of a separate reporting form. §§493.1109(a)(c) Probes: How does the reference laboratory notify the referring laboratory or client of unacceptable specimens in a timely manner? (Cite "timely" deficiencies at D3050 and "reporting information" deficiencies at D3061, as appropriate.) §493.1109(b) Guidelines: Laboratories having a single certificate for multiple sites/location should have a system in place to identify which tests were performed at each site. Use §493.1109(b) only when a laboratory holding a single certificate for multiple sites does not have a system in place to identify which site performed the testing. See §493.1111(c) for citing deficiencies regarding the identity of a reference laboratory where testing is performed.
	§493.1109 Standard; Test report.	
D3043	The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test.	
D3044	The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting.	
D3048	Immunohematology reports must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR Part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).	
D3049	For pathology, test reports must be retained for a period of at least ten years after the date of reporting.	
	This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.	

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D3050	(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and	§§493.1109(a)-(e) Probes: How does the laboratory ensure that transmitted reports are legible and clearly represent the information intended? How does the laboratory maintain confidentiality of patient test reports? If the laboratory uses a laboratory information system, i.e., an electronic reporting system, what security measures have been instituted to ensure that transmitted reports go directly from the device sending reports to only the individual ordering the test or utilizing the test results? If it is possible to access the laboratory information system, how are unauthorized users prohibited from gaining entry? How does the laboratory provide the authorized person ordering tests or using test results with information that is necessary for proper interpretation of the results? How does the laboratory provide its clients with its "normal" or "reference" ranges? Upon request? On the report? In a memorandum/letter? In a brochure? Do the normal or references ranges used reflect the method performed and the population tested? What information does the laboratory provide to the individual ordering or using test results when specimens are unsatisfactory for testing? Is this information relayed in a timely manner? How does the laboratory inform the individual ordering or using a test of the test method employed when it is critical to the interpretation of the test results, e.g., wet mounts for screening fecal specimens for parasites? When the patient's chart or medical report is used as the test report, does the laboratory provide all the required information in a legible and understandable manner? §493.1109(f) Probe: How does the laboratory notify the individual responsible for ordering or using test results of patient test values that are life threatening?
D3054	confidential manner, and ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.	
D3056	(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.	
D3061	(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.	
D3062	(d) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.	
D3063	(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.	
D3064	(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values.	

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D3066	In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.	§493.1109(g) Guidelines: It is not intended that the laboratory maintain an ongoing "list" of the test methods, systems, assays or examinations in use. However, the laboratory must make this information available to its clients upon request. The requirement for a laboratory to establish or verify performance specifications of each method stipulated in §493.1213 does not apply to FDA cleared moderate complexity tests that have not been modified by the laboratory until September 1, 1994. §493.1109(g) Probe: If the laboratory changes methods, establishes a new procedure, or refers tests to another laboratory, how does the laboratory provide the client with necessary updated information concerning parameters such as patient preparation, preservation of specimens, specimen collection, or new "normal" ranges? §493.1109(h) Guidelines: The regulations do not require a laboratory to maintain records including reports on-site. However, during the inspection the laboratory must be able to retrieve copies of all records, reports and necessary information upon request. Determine what constitutes a reasonable time frame based on the information requested. Use §493.1109(h) when the laboratory does not maintain an original or an exact duplicate of the information provided on the test report. If other records, reports or necessary information are not accessible or available, cite deficiencies using appropriate tags under the applicable subpart in which they appear.
D3067	(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, in accordance with §493.1213, as applicable, the performance specifications of each method used to test patient specimens.	
D3069	In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request.	
D3070	Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.	
D3071	(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.	
	§493.1111 Standard; Referral of specimens.	
D3073	A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspeciality of service for the level of complexity in which the referred test is categorized.	

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D3074	(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.	§§493.1111(a)-(c) Guidelines: The laboratory's report must indicate the tests that were performed by a referral laboratory. Test report forms may include codes to identify the name and address of the laboratory that performed the test, providing the interpretations of the codes are available to the authorized person using the test results. Copies of all reports, including corrected reports provided by the referral laboratories must be maintained by both the referral and referring laboratories for the required time periods.
D3075	(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test.	
D3076	The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.	
D3077	(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.	

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D4000	Subpart K - Quality Control For Tests of Moderate or High Complexity, or Both **§493.1201 Condition:General quality control; Moderate or high complexity testing, or both.** (a) Applicability of subpart K of this part. Subpart K is divided into two sections, general quality control and quality control for specialties and subspecialties. The quality control requirements are specified in §§493.1201 through 493.1285 unless-- (1) An alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for general quality control and specialty/subspecialty quality control, and the manufacturer's instructions contain the following statement, "Unless this device is modified by a laboratory, the laboratory's compliance with these quality control instructions will satisfy the applicable requirements of 42 CFR 493.1203(b)." or (2) HHS approves an equivalent procedure that is specified in Appendix C of the State Operations Manual (HCFA Pub. 7). (b) The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. The laboratory must meet the applicable standards in §§493.1202 through 493.1221 of this subpart,	Subpart K Guidelines: At each Condition-level deficiency cited under Subpart K, designate the level of test complexity(ies) that cause the Condition to be out of compliance. (Use "M" (for all devices, products, or test systems cleared by FDA as moderately complex that have not been modified by the laboratory), "H" (high complexity tests, moderate complexity tests that have been modified, developed in-house or not cleared by the FDA), or "B" (for both).) §493.1201 Guidelines: Use D4000 when quality control deficiencies are identified in moderate or high complexity testing, or both, that are significant and have the potential for or adversely affect patient testing, are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty. Significant deficiencies cited under this condition may indicate deficiencies under personnel responsibilities or quality assurance, or both. "Device" , as defined in the Food, Drug, and Cosmetic Act, means "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: o Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, o Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals. . ." The Medical Device Amendments of 1976 expanded the definition of device to include: o Devices intended for use in the diagnosis of conditions other than disease, such as pregnancy, and o In vitro diagnosis products, including those previously regulated as drugs. 21 CFR §809.3 defines "in vitro diagnostic products" as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act . . ." "Modified by the laboratory" means any change in intended use or any change to the assay that could affect the performance specifications, e.g., sensitivity, specificity, accuracy, precision. Examples of changes in intended use are: o Using a different sample matrix (plasma vs. urine); o Using or promoting the test for another purpose (screening vs. diagnostic); and o Changing the type of analysis (qualitative reported as quantitative, and vice versa).

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	unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HHS approves an equivalent procedure specified in Appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Dept. of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487-4630.	Examples of changes to manufacturer's instructions that could affect performance specifications: o Incubation times or temperatures; o Sample or reagent dilution (volume or matrix); o Using a different calibration material (or changing the manufacturer's set-points); o Introducing a different antibody (source, monoclonal-vs-polyclonal); o Change or elimination of a procedural step; o Change or addition of detector(conjugate) or substrate; o Change in the solid phase; o Change in the cutoff or method of calculating the cutoff; o Change in the endpoint or calculation of the endpoint; o Addition of adsorbent; o Change in the strain of antigen in serologic assays; and o Changing the calibrator/reference serum/control value. Exceptions: If the FDA has cleared a manufacturer's reagents and/or calibration materials for an instrument produced by another manufacturer, the use of these reagents/materials is not considered a method modification. Use of reagents that are exempt from the premarket notification procedures in 21 CFR 807 for an instrument produced by another manufacturer is not considered a method modification. The use in automated or semi-automated analyzers of rotors/cuvettes that have been reprocessed (reconditioned), passed quality control inspection criteria of the reprocessing company, and returned to the same laboratory that sent them for cleaning and re-use is not considered a method modification. Manufacturers may assist laboratories by providing quality control instructions. However, the laboratory is responsible for the performance, documentation and interpretation of quality control data. Laboratories using manufacturer's instruments, kits or test systems labeled for "investigational use only", or "research use only" must clearly state that the test results are not to be used for treatment or diagnostic purposes. If such tests are being reported without a disclaimer statement, they are in the same category as in-house developed tests and must meet all applicable requirements in this subpart. To determine which tests are categorized as waived, moderate or high complexity, refer to the "Specific List For Categorization of Laboratory Test Systems, Assays and Examinations by Complexity" as published in the Federal Register. Those test systems, assays and examinations not included in this listing are considered high complexity.

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	§493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1994.	§493.1202 Guidelines: Section 493.1202 will be effective from September 1, 1992, through September 1, 1994. These guidelines do not include instructions for inspecting instruments, kits or test systems cleared by the FDA as meeting the CLIA requirements prior to September 1, 1994. Such instructions will be developed at a later date. On September 1, 1994, §493.1202 becomes obsolete and §493.1203 becomes effective. §493.1202(a) Guidelines: ALL quality control requirements specified in §493.1201 and §§493.1204 through 493.1285 are applicable to each test of high complexity, as appropriate, unless otherwise specified in these guidelines. §493.1202(b) Guidelines: ALL quality control requirements specified in §493.1201 and §§493.1204 through 493.1285 are applicable, as appropriate to each test of moderate complexity that has been: o Developed in-house; o Not subject to clearance by the FDA, e.g., textbook or reference procedures such as Gram stain, direct anti-globulin test, manual peripheral blood smear differentials (this includes commercially distributed instruments, kits or test systems marketed prior to the Medical Device Amendments, Public Law 74-295, enacted on May 28, 1976); or o Cleared by the FDA and modified by the laboratory. §493.1202(c)(1)-(6) Guidelines: For products cleared or approved by the FDA that are moderately complex (that have not been modified by the laboratory), the only quality control requirements that apply are §§493.1202(c)(1) through (6). To evaluate compliance with the requirements at §§493.1202(c)(3)(4) and (5), use the guidelines in §§493.1223-493.1285 for each specialty/subspecialty, as applicable. Cite all quality control recordkeeping deficiencies at D6072 (for moderate) and quality control record retention deficiencies at D8021 and D8023, as appropriate. §493.1202(c)(1) Guidelines: Deficiencies should be cited at D4001, if the laboratory fails to follow manufacturer's instructions that include, but are not limited to: o Handling reagents, materials and supplies; o Adhering to conditions for storage and testing; and o Performing equipment maintenance and function checks. See D4260, Immunology/Syphilis, D4282, Routine Chemistry/Blood Gases, and D4475, Immunohematology for citing specific deficiencies when a laboratory fails to follow manufacturer's instructions in these areas. Following manufacturer's instructions means that the laboratory complies with the requirements (statements such as must or shall) in package inserts and/or instrument operator manuals. Guidance that is not mandatory for the laboratory to follow includes suggestions, advice, or recommendations.
	(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.	
	(b) For each test of moderate complexity performed using a standardized method, or method developed in-house, a device not subject to clearance by the FDA (including any commercially dietributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864 and 866 as exempt from FDA premarket review), or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.	
D4001	(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must-- (1) Follow the manufacturer's instructions for instrument or test system operation and test performance;	

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D4002	(2) Have a procedure manual describing the processes for testing and reporting patient test results;	§493.1202(c)(2) Guidelines: The laboratory may use the manufacturer's package insert or operator's manual. If these inserts or manuals do not include instructions for performance of calibration, control procedures or specialty/subspecialty control activities, remedial action protocol, and reporting patient test results as required under §§493.1202(c)(2), (3), (4), (5), and (6), the laboratory must supplement the manufacturer's instructions to include these items. Processes for testing include procedures for test performance, calibration and control activities. In accordance with §493.1407(e)(13), the laboratory director must ensure that an approved procedure manual is available to testing personnel. (Use D6031.) §493.1202(c),(3),(4) and (5) Guidelines: When a manufacturer's instructions meet or exceed the requirements of §§493.1202(c),(3),(4) and/or (5), the laboratory must follow the manufacturer's instructions. Use D4001 when a laboratory does not follow the manufacturer's instructions. Do not cite §493.1202(c)(1) if manufacturer's instructions are less stringent or do not address the requirements of §§493.1202(c)(2) through (6). Cite performance and/or documentation deficiencies as applicable at §§493.1202(c),(3) and (4). (Use D4003 and/or D4006.) §493.1202(c)(3) Guidelines: The calibration requirement would not apply to a variety of procedures, which include, but are not limited to: o Manual procedures not involving an instrument, i.e., agglutination tests, rapid antigen systems; and o Some procedures involving instruments in which calibration may not be practical, i.e., prothrombin procedures. This requirement is NOT cross-referenced to §493.1217. Therefore, neither the requirements nor guidelines of that section are applicable to §493.1202(c)(3). This is a minimal requirement which may be satisfied if the laboratory performs those procedures designated by the manufacturer as instrument or procedural calibration or calibration checks, as specified by the manufacturer. If the manufacturer requires calibration procedures at an unspecified frequency or less frequently than every 6 months, the laboratory must meet the six-month calibration frequency of this requirement. When the manufacturer does not require calibration procedures, the requirements at §493.1202(c)(3) would not apply. However, the laboratory must ensure the accuracy of the test system and meet the requirements at §§493.1407(e)(3), 493.1413(b)(2), and 493.1709, as applicable.
D4003	(3) Perform and document calibration procedures or check calibration at least once every six months;	

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D4006	(4) Perform and document control procedures using at least two levels of control materials each day of testing;	§493.1202(c)(3) Probes: If calibration materials are not available, or if the manufacturer does not require a calibration procedure, how does the laboratory assure that the system functions properly to provide accurate test results? (Use D6012-D6014, D6040, D6085-D6087, D6115, and D7043, as applicable.) §493.1202(c)(4) Guidelines: The laboratory must follow manufacturer's instructions, but at a minimum, run no less than two levels of control materials each day of testing, unless otherwise indicated in these guidelines. For those products that include controls, e.g., control materials included in the kit, laboratories that test the controls (at least two levels) each day of testing are in compliance with this requirement. This requirement is NOT cross-referenced to §493.1218. Therefore, neither the requirements nor guidelines of that section are applicable to §493.1202(c)(4). Instrument or procedural or electronic control checks (at least two levels) may be used to meet this requirement. For qualitative procedures a positive and negative control will satisfy this requirement. For all specialties and subspecialties, positive and negative controls may be : o Commercially prepared controls or calibration materials; o Previously tested patient specimens provided the laboratory determines the acceptable performance level for the patient specimens; or o Proficiency testing specimens for which results have been confirmed. For exceptions to the control requirements of this section, see the specific specialty/subspecialty areas in §§493.1225 through 493.1285. §493.1202(c)(4) Probes: If control materials are not provided by the manufacturer, what does the laboratory use to assure the validity of test results? §493.1202(c)(5) Guidelines: Guidelines specific to each specialty/subspecialty area are listed in their respective sections, i.e., §§493.1223 through 493.1285. §493.1202(c)(6) Guidelines: See §493.1219(b)-(d) - Remedial action when citing deficiencies for §493.1202(c)(6).
	(5) Perform and document applicable specialty and subspecialty control procedures as specified under §493.1223;	
	(6) Perform and document that remedial action has been taken when problems or errors are identified as specified in §493.1219; and	
	(7) Maintain records of all quality control activities for two years. Quality control records for immunohematology and blood and blood products must be maintained as specified in §493.1221.	

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	§493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994.	§493.1203 Guidelines: §493.1203 is effective on September 1, 1994, and replaces §493.1202. Guidelines will be developed at a later date for inspecting laboratories using products that have been cleared by the FDA as meeting CLIA requirements for quality control.
	For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it: (a) Meets all applicable quality control requirements specified in this subpart when using a standardized method, a method developed in-house, a device not subject to clearance by the FDA (including any commercially distributed instrument, kit or test system subject to the Food, Drug and Cosmetic Act marketed prior to the Medical Device Amendments, Public Law 94-295, enacted on May 28, 1976, and those identified in 21 CFR parts 862, 864, and 866 as exempt from FDA premarket review), a manufacturer's product modified by the laboratory, or a device (instrument, kit or test system) not cleared by the FDA as meeting certain CLIA quality control requirements; or (b) Follows manufacturer's instructions when using a device (instrument, kit, or test system) cleared by the FDA as meeting the CLIA requirements for quality control located at §§493.1215, 493.1217 and 493.1223, and applicable parts of §§493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with requirements of §§493.1204, 493.1213, 493.1219, and 493.1221 and those parts of §§493.1205, 493.1211, and 493.1218 that are unique to the laboratory facility and cannot be met by manufacturer's instructions.	

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	§493.1204 Standard; Facilities	§493.1204 Guidelines: The requirements of §493.1204 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. See §493.1202(c). §493.1204(a) Guidelines: Work areas should be arranged to minimize problems in specimen handling, examination and testing of specimens and reporting of test results. Workbench space should be sufficient for test performance, well lighted, and have water, gas, suction and electrical outlets as necessary. Instruments, equipment and computer systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, vibrations, power fluctuations or fumes from acid or alkaline solutions. Equipment tops should not be used as workbench space. Determination of proper lighting is subjective since the regulations do not specify the foot-candles or other measures of light intensity required. When citing deficiencies, document the circumstances in which lighting adversely or may adversely affect test performance. §493.1204(a) Probes: How does a laboratory ensure its ventilation system properly removes vapors, fumes and excessive heat? How does a laboratory ensure that an adequate, stable electrical source is maintained at each location and meets the power requirements for each piece of equipment? What type of lighting or background is available for visual interpretation of test results (e.g., macroscopic evaluation of hemagglutination reactions)? §493.1204(b) Guidelines: If you observe or obtain information regarding potential safety violations not applicable under CLIA, notify the appropriate State or local authority. Consult with the RO for notification to other Federal agencies such as the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), or Nuclear Regulatory Commission (NRC). The appropriate Federal, State or local authority, if warranted, will investigate and, if necessary, conduct an on-site visit. §493.1204(b) Probes: What safety precautions are posted in the laboratory? Are established safety precautions followed?
D4012	The laboratory must provide the space and environmental conditions necessary for conducting the services offered.	
	(a) The laboratory must be constructed, arranged, and maintained to ensure the space,	
D4016	ventilation, and	
D4017	utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate.	
D4018	(b) Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical and electrical hazards and biohazardous materials.	

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		How does the laboratory, including temporary testing sites or mobile units: o Dispose of radiological, chemical, and biological wastes (including blood drawing equipment); o Clean up spills (chemical, biological, and radiological); and o Determine the amount of waste that can safely be contained and the precautions necessary to ensure that liquid waste does not spill or splash while in travel status? What precautions are employed by laboratory personnel when handling specimens to ensure protection from contamination or infection? What chemical precautions are taken, if any, during the preparation or handling of reagents, solutions and stains?
	§493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.	§493.1205 Guidelines: The requirements of §493.1205 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. See §493.1202(c). §493.1205(a) Probes: Are instruments with adjustable settings appropriately set for each substance or cell to be analyzed?
D4022	The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.	§493.1205(b) Guidelines: If the equipment or instrumentation is found to be inappropriate or insufficient, document the reasons for this finding. (Base deficiencies related to inappropriate or insufficient equipment on a determination that patient results are or may be adversely affected.) When evaluating whether the laboratory has appropriate and sufficient equipment/instruments, reagents, materials, and supplies, consider an assessment of the laboratory's resource management capabilities.
D4023	(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test method as determined under §493.1213.	"Appropriate" means that the test systems, equipment and/or instruments are capable of producing results within the laboratory's stated test performance specifications.
D4024	(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.	"Sufficient" is defined as the test systems, equipment and/or instruments necessary to perform the laboratory's volume of testing (preanalytical, analytical postanalytical) within its established turnaround times.
	(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.	Data space capacity in the laboratory's information system should be sufficient for current data entry. If this space is maintained by deletion of data, it should be scheduled and documented.

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D4025	(1) These conditions include, if applicable-- (i) Water quality; (ii) Temperature; (iii) Humidity; and (iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.	§493.1205(c)(1) Guidelines: Temperature-controlled spaces, equipment, and instruments should be monitored and acceptable temperature ranges must be established and maintained. Each method and piece of equipment should have the humidity and the temperature tolerance limits for operation established and available when necessary and critical to test performance. Continuous monitoring of temperatures by a recording thermograph are acceptable. The charts must be retained to document that temperatures were within the limits established by the laboratory. In lieu of temperature recording, it is acceptable for temperatures to be maintained and monitored internally by an instrument, provided test results either are not generated or are flagged when the temperature range for test performance is exceeded. If alarms of any type, i.e., laboratory information systems, temperature controlled spaces, are used to alert laboratory personnel of an imminent problem, such as power fluctuation, the laboratory should have a system in place to periodically monitor and test alarm performance. (Use D4094-D4097 or D4493, as appropriate.) Water quality has been classified by several different organizations. Each laboratory is expected to use the appropriate water quality as required for each instrument, kit or test system. Laboratories producing water should consider parameters such as pH, silicate content, particulate matter and bacterial and organic content in assessing water quality. These parameters vary by test system and should be assessed by the laboratory for appropriateness and monitoring. Laboratories purchasing water that has already been classified are not expected to evaluate the above parameters unless specified by the manufacturer or by the laboratory in its procedure manual. §493.1205(c)(1) Probes: How does the laboratory provide special conditions when required for specimen or reagent storage, i.e., -70°C for virology, dry ice, amounts of sufficient liquid nitrogen for freezing? How is room temperature and humidity monitored when necessary for test performance or proper operation of reagents, instruments, equipment, or laboratory computer systems? When temperatures and/or humidity are outside acceptable limits, how does the laboratory rectify the problem? §493.1205(c)(1)(iv) Guidelines: The laboratory is not required to monitor equipment or instrument voltage unless specified by the manufacturer. §493.1205(c)(2) Guidelines: Failure to perform and document remedial action related to water quality, temperature, humidity, and stability of electrical supply should be cited here. Refer to §493.1219 for citing other deficiencies related to remedial action.
D4029	(2) Remedial actions taken to correct conditions that fail to meet the criteria specified in paragraph (c)(1) of this section must be documented.	
D4030	(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate-- (1) Identity and, when significant, titer, strength or concentration;	
D4032	(2) Recommended storage requirements;	
D4033	(3) Preparation and expiration date; and	
D4034	(4) Other pertinent information required for proper use.	
D4038	(e) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that-- (1) Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality.	

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D4040	The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics.	§493.1205(e)(1) Guidelines: In citing deficiencies, for outdated or deteriorated materials, whenever possible, indicate whether these materials have been used for patient testing. Look for contamination, drying or other signs of deterioration. This is as important as checking expiration dates. All exceptions for product dating granted by FDA must be maintained by the laboratory for at least a 2-year period after the final use of the reagent/material/kit. (Use D 4041 and/or D4182, or D4184, as appropriate.) §493.1205(e)(1) Probes: How does the laboratory assure that reagents, solutions, and other supplies or materials that require specific conditions for storage and handling are handled and stored properly, e.g., temperature, light, humidity, proper container? Does the laboratory have the appropriate equipment to prepare reagents, stains, solutions, controls, and calibration materials, e.g., pipettes, hydrometers, graduated cylinders, autoclaves, balances, centrifuges, distilled/deionized water? When mobile laboratory or temporary testing site equipment is not in use (weekends, overnight) how are instruments, reagents, stains, and other solutions protected from extreme temperature fluctuations? If "frost-free" freezers are used, how does the laboratory assure that specimens, tissue, reagents, and supplies are not damaged due to the cycle of freezing, thawing and refreezing? §493.1205(e)(2) Guidelines: "Kit" means all components of a test that are packaged together. §493.1211 Guidelines: The requirements of §493.1211 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. (See §493.1202(c).) §493.1211(a) Guidelines: Procedures may be organized in the form of manuals, stored in computers and/or card files and must contain such information as specified in §§493.1211(b)(1) through (16). If the laboratory has procedures that are not used for test performance, but are used for reference purposes, they may be placed in a reference section. You need not review these procedures unless problems are identified with patient test results. CDC manuals, manufacturer's operating instructions, package inserts and manuals such as the Armed Forces Institute of Pathology (AFIP) manual are acceptable provided that the policies and procedures listed in §§493.1211(b)(1) through (16) are available and the methods in use are clearly indicated.
D4041	Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and	
D4042	(2) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.	
	§493.1211 Standard; Procedure manual.	
D4043	(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel.	
	Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.	

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	(b) The procedure manual must include, when applicable to the test procedure:	After September 1, 1992, if the laboratory modifies any procedure, the modification must be documented and verified as specified in §493.1213.
D4046	(1) Requirements for specimen collection and processing, and	Cite failure to follow the laboratory's written procedures for test performance for cytology tests at D4043. For moderate complexity testing, use D6070, and for high complexity testing use D6175.
D4048	criteria for specimen rejection;	§493.1211(a) Probes: How does the laboratory ensure that personnel follow the procedures in the procedure manual? How are changes in procedures communicated to bench personnel?
D4049	(2) Procedures for microscopic examinations, including the detection of inadequately prepared slides;	
D4050	(3) Step-by-step performance of the procedure, including test calculations and interpretation of results;	§493.1211(b)(4) Guidelines: The identity and concentration of the calibrator(s), the number to be used and the calibration and calibration verification schedule should be specified. The calibration and calibration verification protocol must correlate with calibration and calibration verification performed under §493.1217(b).
D4051	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;	
D4052	(5) Calibration and calibration verification procedures;	
D4054	(6) The reportable range for patient test results as established or verified in §493.1213;	§493.1211(b)(7) Guidelines: For each test procedure, the type of control (manufacturer or in-house), identity (normal, abnormal, level I, II etc.), number and frequency of testing controls should be defined and include the criteria for determining the acceptability of control results. Control limits must be established in accordance with §493.1218(d) and must be available to testing personnel. Control limits may be included in the procedure manual.
D4055	(7) Control procedures;	
D4056	(8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;	
D4057	(9) Limitations in methodologies, including interfering substances;	§493.1211(b)(10) Guidelines: Defined reference ranges including the range of values for each type of specimen, i.e., urine, serum, and demographic variables such as age and sex, as applicable, should be available to bench personnel.
D4058	(10) Reference range (normal values);	
D4059	(11) Imminent life-threatening laboratory results or "panic values";	
D4060	(12) Pertinent literature references;	
D4061	(13) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;	

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D4062	(14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;	§493.1211(b)(14) Guidelines: If a laboratory uses a computer system for processes such as result entry or worksheet generation, the procedures for computer use should be available and include whom to call for assistance when there are problems with the device or system being used. Procedures that contain the information necessary for proper operation and reporting must be available to operators of laboratory information systems (LIS). Instructions should contain the individual(s), either by name or position, to notify if the LIS goes down or if a system error occurs. §§493.1211(d)-(f) Guidelines: All laboratory procedures including CDC and AFIP manuals, manufacturer's operator manuals and package inserts must reflect the director's review and approval of any modifications in the procedure. Approval of procedures is the responsibility of the laboratory director. A coversheet may be used for the director to approve the manual. Annual review of procedures is not required, unless there is a change in director or the individual to whom this responsibility is delegated.
D4063	(15) Description of the course of action to be taken in the event that a test system becomes inoperable; and	
D4064	(16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in §493.1103.	
	(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.	
D4065	(d) Procedures must be approved, signed, and dated by the director.	
D4066	(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.	
D4067	(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory.	
D4068	(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance.	
D4069	These records must be retained for two years after a procedure has been discontinued.	

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	§493.1213 Standard; Establishment and verification of method performance specifications.	§493.1213 Guidelines: The requirements of §493.1213 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. (See §493.1202(c).) Guidelines for determining compliance with these requirements are located in the respective specialty/subspecialty sections at §§493.1223-493.1285. §493.1213(b)(1) Guidelines: These requirements are not effective until instruments, kits, or test systems have been cleared by the FDA as meeting CLIA requirements. Guidelines are to be developed at a later date to address products cleared by FDA as meeting CLIA requirements.
	Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and any other applicable performance characteristic.	
	(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.	
	(b)(1) Each laboratory that introduces a new procedure for patient testing using a device (instrument, kit, or test system) cleared by FDA as meeting certain	

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	CLIA requirements for quality control, must demonstrate that,	§§493.1213(b)(2) Guidelines: This requirement applies **only** to high complexity methods and moderate complexity methods that have been developed in-house, methods not subject to FDA clearance, e.g., Gram stain examinations, direct anti-globulin tests, manual microscopic peripheral blood smear differential, or commercial test methods cleared by the FDA that have been modified by the laboratory. Although no specific guidelines exist for verifying or establishing performance specifications of a test method, each laboratory is responsible for determining the performance specifications of the test methods in use. Verification/establishment of accuracy, analytical sensitivity and specificity, and reference range may be accomplished by, but is not limited to: o Thoroughly testing reference materials or comparing results of tests performed using an established alternative reference method; or o If reference materials or established alternative reference methods are not available, by comparing split sample results with results obtained from a method which is shown to provide clinically valid results. The verification/establishment of method specifications should provide evidence that the accuracy, precision, analytical sensitivity, and analytical specificity of the procedure is adequate to meet the physicians' needs in managing their patient's health care, as determined by the clinical consultant. For each commercial test method, a laboratory may use the manufacturer's performance specifications as a guideline, but must verify the manufacturer's claims before initiating patient testing. Through the verification process, the laboratory defines the schedule for calibration and control procedures and the number and concentration of calibration and control materials to be used to monitor and evaluate method performance. The schedule for calibration and control procedures should not be less than the frequency specified in the manufacturer's instructions. At the time of verifying or establishing method performance specifications, the laboratory determines the upper and lower limits for reporting patient results. Thereafter, the reportable range of patient test results is monitored by calibration verification as required under §493.1217(b)(2), which must include calibration materials that monitor the upper, lower and mid-range used for reporting patient test results. For some qualitative tests, the laboratory may verify the manufacturer's specifications by running known positive and negative samples to assure that the expected results are obtained. Specimens of known quantitative value may be used to determine the laboratory's performance specifications for a qualitative test. Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.
	prior to reporting patient test results,	
	it can obtain the performance specifications for accuracy,	
	precision, and	
	reportable range of patient test results, comparable to those established by the manufacturer.	
	The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.	
	(2) Each laboratory that introduces a new method or device as specified in either §§493.1202(a) or (b), or §§493.1203(a) must, prior to reporting patient test results--	
D4074	(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable: (A) Accuracy; (B) Precision; (C) Analytical sensitivity; (D) Analytical specificity to include interfering substances; (E) Reportable range of patient test results; (F) Reference range(s); and (G) Any other performance characteristic required for test performance.	

<table>
<tr><th colspan="3">INTERPRETIVE GUIDELINES - LABORATORIES</th></tr>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td></td><td>(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish</td><td rowspan="3">For all quantitative methods, the laboratory must establish or verify the accuracy, precision, analytical specificity and analytical sensitivity, reportable range of patient test results and reference range(s).

If a laboratory relocates or changes testing sites, it must document that its established performance specifications for each test method are not affected by the relocation of the laboratory or test system.

§§493.1213(b)(2) Probes:
Do the verification records reflect the current methods and instrumentation used for test performance? (At least twice a year, the laboratory must define the relationship between testing performed at different testing sites and testing performed using different instruments, kits, or test systems.) (Use D7043.)

If a method was verified by someone other than the laboratory staff (i.e., manufacturer representative), how did the laboratory demonstrate that this verification correlates with its in-house test performance?

If a laboratory has developed a procedure, or modified a manufacturer's instructions, how did it determine it's clinical sensitivity and specificity?

How did the laboratory evaluate patient specimen values in determining the appropriateness of the normal/reportable range?

Accuracy- How did the laboratory determine that the method produces correct results? For qualitative methods, how did the laboratory verify that a method will identify the presence or absence of an analyte?

Precision- How did the laboratory evaluate the precision of automated tests and manual tests, including operator variance, which can be assessed through testing personnel performance evaluations and automated tests, e.g., assessment of day-to-day, run-to-run, within-a-run variation?

Analytical Sensitivity- Can the lowest concentration or amount of the analyte or substance be measured or distinguished from a blank, e.g., minimum detection limits. In many instances verification of the manufacturer's reportable range will satisfy this requirement. Otherwise, how much of the analyte must be present to be measured?

Analytical Specificity/Interfering Substances- Is the extent to which the method responds to only the analyte or substance to be measured. How did the laboratory determine that the method measures only the analyte it is reporting, i.e., in-house procedures, modified manufacturer's products?</td></tr>
<tr><td>D4081</td><td>calibration and control procedures for patient testing as required under §§493.1217 and 493.1218.</td></tr>
<tr><td>D4083</td><td>(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.</td></tr>
</table>

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		What disease states, treatments, or antibiotics, are known to cause interference or affect the methods in use? Reportable Range- For each test method, how did the laboratory establish or verify reportable range of patient test results (for the type of specimen and demographic variables such as age and sex, as applicable)? Reference Range- The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population. If a laboratory has developed a procedure or modified a manufacturer's procedure, how did the laboratory determine the normal range(s)? Other Performance Characteristics- How did the laboratory determine counting times for RIA procedures? How did the laboratory ensure that patient results are valid if the matrix of the calibrators and/or control materials differs from the matrix of patient specimens? §§493.1213(c) Probes: What data does the laboratory have to demonstrate the establishment or verification of its performance specifications for each test method?
	§§493.1215 Standard; Equipment maintenance and function checks.	§§493.1215 Guidelines: The requirements of §493.1215 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. (See §493.1202(c).) The laboratory must establish and follow procedures for performing maintenance and function checks on each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing, e.g., incubators, centrifuges, safety cabinets, autoclaves. The laboratory must follow and document the necessary maintenance stated by the laboratory information system (LIS) manufacturer or established by the laboratory for the LIS computer and components such as monitors, printers and modems. All input/output components, such as monitors, printers, and modem transmission equipment must be maintained to assure accurate, clear, and interference-free transmission. If the LIS performs any calculation functions to determine a laboratory result, the function should be verified immediately after the LIS is programmed and prior to calculation of patient results.
D4084	The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports.	

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	(a) Maintenance of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must--	§§493.1215 Probes: How does the laboratory determine if a new or revised LIS program (whether purchased or developed in-house), performs acceptably before it is integrated into routine operation? Are LIS master packs or master memory components maintained and stored according to the manufacturer's instructions? When downtime is required to perform maintenance functions on LIS equipment, how does the laboratory provide ample notification to LIS users? (Use D4177 if patient results are not reported within established timeframes.) §§493.1215(a)(1) Guidelines: These requirements are not effective until September 1, 1994, or until instruments, kits, or test systems have been cleared by the FDA as meeting CLIA requirements. Guidelines will be developed at a later date to address products cleared by FDA as meeting CLIA requirements. §§493.1215(a)(2) Guidelines: A laboratory's maintenance program is usually divided into two parts: o Unscheduled repairs when needed; and o Scheduled preventive maintenance (PM) which is performed to prevent breakdowns or malfunctions, to prolong the life of an instrument and to maintain optimum operating characteristics. A service contract for PM from an outside source is acceptable provided that for each instrument or piece of equipment, there is a description of the service to be performed and frequency of service. A service contract does not negate the laboratory's responsibility for performing other routine maintenance not included in the maintenance contract. Acceptable performance parameters (if applicable) must be documented. §§493.1215(a)(2) Probes: How does the laboratory's maintenance program assure that instruments and equipment maintain optimum operating characteristics and minimize breakdowns? What type of documentation does the laboratory have to reflect the preventive maintenance activities performed? When there is major preventive maintenance or replacement of parts critical to the testing system, e.g., column changes in chromatograph instruments, does the laboratory redefine or verify the reportable range of patient testing as necessary? (Use D4121.) In immunofluorescent test procedures, how does the laboratory assure that the bulb is emitting ultraviolet light?
	(i) Perform maintenance as defined by the manufacturer and	
	with at least the frequency specified by the manufacturer; and	
	(ii) Document all maintenance performed.	
	(2) For methods or devices, as specified in either §493.1202(a) or (b) or §§493.1203(a), the laboratory must--	
D4088	(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;	
D4089	(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and	
D4090	(iii) Document all maintenance performed.	

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	(b) Function checks of equipment, instruments, and test systems. (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must--	§§493.1215(b)(1) Guidelines: These requirements are not effective until September 1, 1994, or until instruments, kits, or test systems have been cleared by the FDA as meeting CLIA requirements. Guidelines are to be developed at a later date to address products cleared by FDA as meeting CLIA requirements. §§493.1215(b)(2) Guidelines: Function checks refer to those activities performed to evaluate critical operating characteristics, e.g., stray light, zeroing, electrical levels, optical alignment, background counts, counting efficiency, according to the accepted method of operation for each type of device or instrument. Daily activities and checks are performed prior to patient testing to ensure that an instrument is functioning correctly and is properly calibrated, e.g., checking electrical, mechanical and operational functions may be independent of the procedure. The performance of daily control activities may serve as an instrument function check, since analysis of control samples check the operating characteristics of a test system, including instrument stability and calibration. For instruments which automatically perform function checks and flag problems, the laboratory is required to document the corrective actions in response to the flagged problems. (Cite deficiencies related to remedial action under D4170-D4172. Cite deficiencies related to documentation of remedial actions under D4182.) Flow cytometry: A fluorescence standard(s) for each fluorochrome should be used each day of patient testing to insure: o Proper alignment of the optical system; o Standardization of the fluorescence detectors; o Resolution of dimly-stained particles; and o Appropriate compensation for spectral overlap of the fluorochromes. The fluorescence standards should have the same fluorochromes incorporated into them as are used for the test, and with the exception of alignment standards, should have similar fluorescence intensities as found in the test specimens. The laboratory should have an acceptable range of performance for all procedures. For flow cytometers with air-cooled lasers, the laser should be tested each day patients are tested by peaking the laser signal and monitoring the current input (amps) to laser light output (milliwatts) to determine whether the brewster windows are in need of cleaning. For laser-based flow cytometer instruments having brewster windows, the ratio of current input (amps) to laser light output (milliwatts) at the normal operating wavelength, measured after the laser is peaked and normal operating power set, should be used as an indicator of dirt accumulation, and the need for cleaning of optics.
	(i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and	
	(ii) Document all function checks performed.	
	(2) For methods or devices, as specified in either §493.1202(a) or (b) or §493.1203(a), the laboratory must--	
D4094	(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;	
D4095	(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section.	
D4096	Function checks must be within the laboratory's established limits before patient testing is conducted; and	
D4097	(iii) Document all function checks performed.	

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		§§493.1215(b)(2) Probes: When autoclaves are used for laboratory purposes, what systems are in place to assure that autoclaves are functioning properly? For procedures or test systems that require pipetting or dilution of patient samples separately from controls or calibrators, how are autodiluters, microdiluters, and/or pipettors, verified for precision and accuracy? Are cell washers, autodilutors and auto washers that process patient samples separately from controls and calibrators checked for adequate and consistent delivery? For those systems that perform simultaneous fluid delivery to multi-well plates or tubes, how does the laboratory assure uniform delivery of reagents or washing solutions to all wells or tubes? What records are maintained to document that a mobile laboratory, or one that moves from testing site to testing site has equipment that maintains operational characteristics? What type of documentation does the laboratory have to reflect the actual measurement(s) taken or observed? Are the actual measurements within the tolerance limits defined for function checks and are the measurements documented? When function checks are critical to test performance, what mechanisms are in place to monitor such items as: o Rotator speed and circumference; o Timers; o Anaerobic chambers; o Cell washers; o Radioactive particle counters; and o Blood cell counters? If function checks are not required or recommended by the manufacturer, how does the laboratory verify the performance of its equipment and instruments? Are backgrounds or baselines measured for each setting? For example, if the laboratory uses more than one type of isotope, at what window setting are background counts performed and recorded? Flow Cytometry What action does the laboratory take when an unacceptable difference is noted for the: o Alignment; o Standardization; o Resolution of dim signals; or o Spectral compensation from the previous day? (Use D4170.)

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		When performing analysis using two or more fluorochromes simultaneously, how does the laboratory identify and adjust for "spill over" into the other fluorescence detectors?
	§493.1217 Standard; Calibration and calibration verification procedures.	§493.1217 Guidelines: The requirements of §493.1217 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. (See §493.1202(c).)
D4098	Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results.	Additional guidelines for determining compliance with these requirements are located in the respective specialty/subspecialty sections at §§493.1223 - 493.1285. For calibration and calibration verification of blood gas analysis, see §493.1245(a)-(d), which is applicable in lieu of §493.1217. For calibration and calibration verification of hematology procedures, see §§493.1253(a)-(d), which is applicable in lieu of §493.1217.
	Calibration is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range of patient test results is the range of test result values over which the laboratory can establish or verify the accuracy of the instrument, kit or test system measurement response.	Calibration of procedures is not to be confused with function checks which is noted in §493.1215. However, in many instances, the performance of method calibration serves to satisfy the requirement for instrument calibration. The calibration requirement would not apply to a variety of procedures, which include, but are not limited to: o Manual procedures not involving an instrument, e.g., manual Kirby-Bauer disc susceptibility test, manual tilt-tube prothrombin time test systems, ABO group and D(Rho) typing; o Some procedures involving an instrument in which calibration may not be practical, e.g., HIV antibody by ELISA; and o Microscopic procedures, e.g., KOH preparations, pinworm preparations, urine sediment analysis, all manual differential procedures, cytology screening procedures.
	Calibration and calibration verification must be performed and documented as required in this section unless otherwise specified in §§493.1223 through 493.1285.	The term "calibration material" has generally replaced "standard" since many instruments now use serum based reference materials. "Calibration material" means a solution which has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference or definitive test method. Calibration material may be traceable to a National Institute for Standards and Technology (NIST) Standard, if possible. Control activities routinely used to satisfy the requirement for §493.1218 may not be used to satisfy the calibration verification requirements at §493.1217.

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	(a) For laboratory test procedures that are performed using instruments, kits, or test systems that have been cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.	§§493.1217(a) Guidelines: These requirements are not effective until September 1, 1994, or until instruments, kits, or test systems have been cleared by the FDA as meeting CLIA requirements. Guidelines are to be developed at a later date to address products cleared by FDA as meeting CLIA requirements.
	(b) For each method or device, as specified in either §493.1202(a) or (b) or §493.1203(a), the laboratory must-- (1) Perform calibration procedures--	
D4101	(i) At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer; and	§§493.1217(b)(1) Guidelines: Frequency of calibration is based on the manufacturer's recommendations and calibration verification results. If calibration proves less stable than the manufacturer's recommendation, more frequent calibration may be required, as established or verified by the laboratory under §493.1213. Records must document the frequency of calibration. (Use D4182.)
	(ii) In accordance with criteria established by the laboratory, as required under §493.1213(b)(2)(i)	For each methodology, a laboratory's calibration procedure must, at a minimum, meet the manufacturer's specifications and, when necessary, incorporate any additional calibration materials as determined by the laboratory in §493.1213.
D4105	(A) Including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and	§§493.1217(b) Probes: At what intervals are the method or test system's calibration or calibration verification performed? How often is calibration recommended by the manufacturer or required by the laboratory? What calibration frequency is reflected in the laboratory's records?
D4110	(B) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and	If the laboratory calculates values for one or more calibration materials, are the calculations correct, and do the records reflect that the measured values are within the laboratory's established limits for the calibration materials?

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D4111	(iii) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and	§493.1217(b)(2) Guidelines: For each quantitative test method or analytical system, the laboratory must evaluate the stability of calibration and other operating characteristics in establishing the calibration verification schedule, as determined in §493.1213. Additional calibration materials must be tested as "unknowns" to verify reportable range (upper, lower, and mid-range) of patient test results. The laboratory should define acceptable limits for the difference between the measured value obtained for the calibration materials, versus the actual concentration of the calibration materials. Use appropriate calibration materials as defined under §493.1217 Guideline for calibration verification. When reviewing the laboratory's maintenance and function check records as required in §§493.1215, determine whether the laboratory performed calibration verification, where applicable, when major maintenance occurred or critical parts were replaced. Examples of replacement of critical parts may include, but are not limited to: o Replacement of HPLC and GC columns; o Filters for optical density measurement; o Electrodes; or o Flow cells. §§493.1217(b)(2) Probes: What action does the laboratory take when controls reflect an unusual trend or are outside of acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem? §§493.1217(b)(3) Probes: If a laboratory does not perform calibration verification after a complete change of reagents, what data does the laboratory have to document that changing reagent lot numbers does not affect the reportable range of patient test results, and does not adversely affect control results?
	(2) Perform calibration verification procedures--	
D4113	(i) In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified in paragraph (b)(2)(ii) of this section; or	
	(ii) In accordance with criteria established by the laboratory-	
D4115	(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification;	
D4117	(B) Using calibration materials appropriate for-- (1) The methodology and, if possible, traceable to a reference method or reference material of known value; and	
D4118	(2) Verifying the laboratory's established reportable range of patient test results, which must include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and	
D4119	(C) At least once every six months and	
D4120	whenever any of the following occur: (1) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test	

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	results, and control values are not adversely affected by reagent lot number changes.	
	NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number;	
D4121	(2) There is a major preventive maintenance or replacement of critical parts that may influence test performance;	
D4122	(3) Controls reflect an unusual trend of shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or	
D4123	(4) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in paragraphs (b)(2)(ii)(C)(1), (2), or (3) of this section; and	
D4124	(3) Document all calibration and calibration verification procedures performed.	
	§493.1218 Standard; Control procedures.	
	Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of patient test results.	

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	Control procedures must be performed as defined in this section unless otherwise specified in §§493.1223 through 493.1285 of this subpart.	§§493.1218(a) Guidelines: These requirements are not effective until September 1, 1994, or until instruments, kits, or test systems have been cleared by the FDA as meeting CLIA requirements. Guidelines are to be developed at a later date to address products cleared by FDA as meeting CLIA requirements. Additional guidelines for determining compliance with these requirements are located in the respective specialty/subspecialty sections at §§493.1223 - 493.1285. §§493.1218(b) Guidelines: The requirements of §493.1218 do not apply to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. (See §493.1202(c).) In establishing the quality control frequency, the laboratory should consider: o Instrument/reagent stability, including relocation; o Frequency that the test is performed; o Technique dependence of the method; o Frequency of quality control failures; and o Training and experience of technical personnel. When patient specimens are used to meet the control requirements, data must be evaluated in accordance with §493.1218(d). When calibrators are used in lieu of controls, the calibrators should not be the same calibration materials used to calibrate the test system. A calibrator of a different level should be used. Acceptable ranges must be verified or established by the laboratory for control materials and any calibrators that are used in lieu of control materials. For all specialties and subspecialties, positive and negative controls may be : o Commercially prepared controls or calibration materials; o Previously tested patient specimens provided the laboratory determines the acceptable performance level for the patient specimens; or o Proficiency testing specimens for which results have been confirmed. §§493.1218(b) Probes: What data does the laboratory have to support its frequency of testing quality control samples? How does a mobile laboratory evaluate instrument and reagent stability following relocation to determine the frequency of testing quality control samples?
	(a) For each device cleared by the FDA as meeting certain CLIA requirements for quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for control procedures.	
	In addition, the laboratory must meet the requirements under paragraphs (c) through (e) of this section and, as applicable, paragraph (f) of this section.	
	(b) For each device, as specified in either §493.1202(a) or (b) or §493.1203(a), the laboratory must evaluate	
D4127	instrument and reagent stability and	
D4128	operator variance in determining the number, type, and frequency of testing calibration or control materials and	
D4129	establish criteria for acceptability used to monitor test performance during a run of patient specimen(s).	
	A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours or lesss than the frequency recommended by the manufacturer.	
D4131	For each procedure, the laboratory must monitor test performance using calibration materials or control materials or a combination thereof.	

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D4132	(1) For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.	§§493.1218(b)(2) Guidelines: This requirement is applicable to quantitative tests not governed by the quality control requirements of §493.1202(c). For monitoring the abnormal range, the laboratory should select controls that correlate with the patient values either in terms of specimen matrix or range to be evaluated. (For example, an elevated bilirubin control should be employed when measuring neonatal bilirubins; a low level protein control or cerebrospinal fluid control should be used for monitoring cerebrospinal fluid protein.) §§493.1218(b)(2) Probes: How does the laboratory evaluate the control results required under §493.1218(b) to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system? If more than one method is in use for a test procedure, did the laboratory evaluate the data for each method in the establishment of control limits?
D4135	(2) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in §493.1218(b), but not less frequently than once each run of patient specimens.	
D4138	(3) For electrophoretic determinations-- (i) At least one control sample must be used in each electrophoretic cell; and	
D4139	(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.	
D4140	(4) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract).	
D4142	When direct antigen systems include an extraction phase, the system must be checked each day of use using a positive organism.	
D4144	(5) If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results.	§493.1218(b)(5) Guidelines: Laboratories may choose to split samples for testing by another method to evaluate the results obtained. Precision is determined through replicate testing of a previously tested patient specimen. The duplicate tests may be performed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates.
D4145	(c) Control samples must be tested in the same manner as patient specimens.	§493.1218(c) Guidelines: Controls of a similar matrix to that of patient specimens should be utilized, if available, and the controls must be treated in the same manner as patient samples and go through all test phases. Flow Cytometry In cell surface phenotyping by flow cytometry or fluorescent microscopy, control samples must be analyzed within the same time period after staining as test samples.

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D4146	(d) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing.	§§493.1218(c) Probes: Flow Cytometry How did the laboratory establish the time period in which stained cells must be analyzed to avoid significant loss of any cell subpopulations or total cell numbers? If analysis will be based on a population of cells selected by flow cytometry "gating" on size or density parameters, or selected by depletion or enrichment techniques, are controls tested with each patient to detect the presence of contaminating cells in the selected population? Example: Monocyte contamination of "lymphocytes" gated by forward angle or forward angle versus 90° light scatter should be detected with a monocyte- specific antibody. §§493.1218(d) Guidelines: For procedures in which a spiked sample is used as a control, an acceptable range must be established for the amount of recovery of the spiked sample, either in percentage or actual concentration. When reviewing a sample of patient reports, note if test results were reported despite a control failure (D4150), equipment malfunction (D4170), or when methodology performance specifications are exceeded (D4170). Determine whether the laboratory's documentation of control limits permits identification of lot numbers of controls. (Use D4182.) If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits. There are no specific guidelines for the number of times a material must be tested to establish statistical limits. In general, twenty replicate tests should be considered the minimum. §§493.1218(d) Probes: What statistics does the laboratory have to demonstrate the number of assays and the period of time in which the laboratory repetitively tested control materials to verify or establish control limits? §§493.1218(f) Guidelines: Review the laboratory's quality control records and note when lot numbers change. Note: Media checks are defined under §493.1225.
D4147	(1) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory.	
D4149	(2) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.	
D4150	(e) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.	
	(f) Reagent and supply checks.	
D4151	(1) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.	
D4154	(2) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.	

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D4156	(3) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this subpart).	The laboratory must demonstrate that each reagent performs within the specifications established by the laboratory for the test procedure. Documentation of concurrent testing of reagents or acceptable quality control results will satisfy this requirement. Flow Cytometry Staining controls for cell surface immunophenotyping by flow cytometry should consist of either normal, cultured or abnormal cells known to be positive for selected standard antigens and must verify the proper performance of reagents. Frozen or other preserved cells may be used. A negative reagent control should be run for each test cell preparation, and is to consist of monoclonal antibody(ies) of the same species and isotype. Negative reagent controls will consist of: (a) For indirect stains, an irrelevant primary antibody, if available, and in all cases, the same secondary antibody(ies) conjugated with the same fluorochrome(s) used in all relevant test combinations; and (b) For direct stains, an irrelevant antibody conjugated to the same fluorochrome and at the same fluorochromes:protein ratio used in all relevant test combinations. §493.1218(f) Probes: For flow cell cytometric surface immunophenotyping, is a negative reagent control used to define a threshold for positive staining cells? If not, how does the laboratory define the threshold for positive staining cells? (Use D4156.)
D4159	(4) The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile, and sterility is required for testing.	
D4160	Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response.	
	The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control.	
D4163	The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer.	
D4165	The laboratory must follow the manufacturer's specification for using the media and be responsible for the test results.	
	NOTE: A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.1219 Standard; Remedial actions.	§§493.1219(a) Guidelines: Beginning September 1, 1992, the requirement at §493.1219(a) is not applicable to products cleared or approved by the FDA that are moderately complex unless they have been modified by the laboratory. However, the requirements at §§493.1219(b)-(d) are applicable. §§493.1219(a)(1) Probes: What policies or procedures does the laboratory follow when equipment malfunctions or a test method problem is identified? Are there records to document corrective actions taken by the laboratory? §§493.1219(a)(2)(3) Guidelines: "Less than" is used for reporting test results (qualitative or quantitative) that are below the laboratory's detection limits for an analyte. (Detection limits must be established through method verification as described in §493.1213.) "Equivalent designation" is used to report test results for those methods that yield results below a clinically significant level, e.g., for a quantitative immunology test, patient results may be clinically negative at a 1:8 titer and test results may be reported as "1:8 negative". (The normal range is 1:8 or less.) §§493.1219(a)(2) Probe: What corrective actions are taken for patient results that exceed or fall below the laboratory's reportable range of patient test results? If a dilution procedure is used, how does the laboratory assure the appropriate diluent is used for each type of specimen? (Use D4022.) How does the laboratory verify and document the accuracy of the results for diluted specimens? (Use D4074.) §§493.1219(b)-(d) Guidelines: In accordance with §493.1202(c), these requirements apply to all instruments, kits, and test systems used by the laboratory. The laboratory must either establish its own limits for controls and calibration materials or use the manufacturer's limits. Since §§493.1217 and 493.1218 are not applicable to products cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D4173 to cite deficiencies related to absence of limits for control(s) and calibration materials. §§493.1219(b) Probes: When suboptimal staining or improper coverslipping are identified through quality control procedures, what corrective actions are taken by the laboratory? How does the laboratory assure the accuracy of patient test results, when control specimens are not tested at the same time or if the control sample in the following run fails to fall within defined limits?
D4166	Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports.	
	The laboratory must document all remedial actions taken when-- (a) Test systems do not meet the laboratory's established performance specifications, as determined in §493.1213 of this section, which include but are not limited to--	
D4170	(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;	
D4171	(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and	
D4172	(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.	
D4173	(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability.	
D4174	All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4177	(c) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and	§493.1219(c) Guidelines: Allow some flexibility in evaluating the laboratory's compliance with established time frames for patient testing. Cite deficiencies only when delays in testing patient specimens have the potential for or adversely affect patient care. §493.1219(c) Probes: How does the laboratory handle patient specimens during "downtimes?" What criteria has the laboratory established for notifying the appropriate individual of the delay in testing? §493.1219(d) Guidelines: When determining whether the laboratory gave prompt notification of test and/or reporting errors, to the authorized person(s) consider: o When the error was identified and when the authorized person was notified; and o Extent of error, i.e., clinically significant; results reported on the wrong patient. The laboratory must have a system for maintaining copies of both the original and corrected reports, including computer generated reports. NOTE: Immunohematology reports must be maintained for a minimum of 5 years and pathology reports must be maintained for 10 years. (Use D4181, D3048, or D3049, as applicable.) §493.1219(d)(3) Guidelines: For the definition of exact duplicate, see §493.1109. §493.1219(d) Probes: What mechanism(s) does the laboratory use for notifying the authorized person of the corrected values? Do the corrected reports clearly indicate that they are corrected reports? Use D4180. For corrected reports in cytology, use D4365. For laboratories that maintain test result reports as part of the patient's medical record, is there a mechanism for documenting and maintaining corrected reports? Use D4181. How does the laboratory assure that incorrect original results are not reissued either verbally or in writing? (Use D4174.)
D4178	(d) Errors in the reported patient test results are detected.	
D4179	The laboratory must-- (1) Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;	
D4180	(2) Issue corrected reports promptly to the authorized person ordering the test or the individual utilizing the test results; and	
D4181	(3) Maintain exact duplicates of the original report as well as the corrected report for two years.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.1221 Standard; Quality control records.	§493.1221 Guidelines: This requirement is not applicable to testing using products cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory. Use D8021 and D8023 to cite deficiencies related to failure to maintain quality control records. All QC records must be maintained for two years including instrument charts, graphs, printouts, transcribed data, manufacturer's assay information sheets for control and calibration materials. Records may be stored off-site provided the laboratory can produce the records for review during the survey. §493.1221 Probes: What records does the laboratory have to demonstrate that controls are tested when shipments of reagents, discs, stains, antisera or identification systems are opened or when the laboratory prepares these materials? (Use D4182 for not recording performance, D4151 for nonperformance of quality control checks, and D4154-4156, as applicable, for nonperformance of stain checks.) What information is documented on the quality control records? NOTE: The actual measurement(s) taken, reactions and/or observations should be recorded. However, do not dictate the acceptable format for documentation. Are quality control samples tested at the same time patient specimens are tested? Use D4145 for deficiencies related to performance and D4182 for record keeping. Do the records of a laboratory that moves from testing site to testing site demonstrate the performance of control samples following transport of equipment when such activity affects test performance specifications and/or instrument calibration? Use D4182.
D4182	The laboratory must document and maintain records of all quality control activities specified in §§493.1202 through 493.1285 of this subpart and retain records for at least two years.	
D4184	Immunohematology quality control records must be maintained for a period of no less than five years.	
D4185	In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.1223 Condition: Quality control - specialties and subspecialties for tests of moderate or high complexity, or both. The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to ensure the accuracy and reliability of patient test results and reports. Except as specified in §493.1202(c), the laboratory must meet the applicable general requirements specified in §§493.1201 through 493.1221. In addition, the laboratory must meet the applicable requirements of §§493.1225 through 493.1285 unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting certain CLIA requirements for quality control or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7).	§493.1223 Guidelines: Instructions will be provided by September 1, 1994 for inspecting instruments, kits, or test systems cleared by FDA as meeting CLIA requirements for quality control.
	Failure to meet any of the applicable conditions in §§493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§493.1225 Condition: Microbiology. The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and in §§493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.	§493.1225 Guidelines: If a laboratory screens cultures for growth or no growth, reports "No growth" and refers all growth to a reference laboratory, the screening laboratory must perform applicable quality control of the media. For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, the manufacturer's instructions for media checks must be followed. For all other test systems, each batch of media, either commercially produced or prepared by the laboratory must be tested. A batch or shipment refers to all the discs, stains, antisera, and reagents including identification systems prepared at the same time in the laboratory or having the same lot number, that are received in a single shipment from an outside source or commercial supplier. A sample of the batch is sufficient as a check for: o Sterility, if it is autoclaved or filtered during preparation (use D4159); o Ability to support growth, using at least one organism to demonstrate the ability of the media to support growth (use D4160); o Selectivity and/or inhibition, using at least one organism to confirm its selective characteristic, and at least one organism to confirm it's inhibitory characteristic (use D4160); and o Biochemical response, using at least one organism which will produce the expected reaction (positive control) and with at least one organism which will not produce the expected reaction (negative control). (Use D4160.) EXCEPTION: A laboratory using commercially prepared microbiological culture media that is quality controlled in accordance with the NCCLS Approved Standard (M22-A) Table 3 (Insert) need not perform quality control checks for sterility, growth, selectivity and/or inhibition and biochemical responses provided: o The laboratory has documentation on the media label or brochure that the quality control practices conform to NCCLS specifications; and o The laboratory documents receipt and condition of each batch of media, and notifies the media manufacturer of: - Cracked petri dishes; - Unequal filling of plates; - Cracked media in plates; - Hemolysis; - Freezing; - Excessive number of bubbles; and - Contamination.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		This exception does not apply to: o Campylobacter agar; o Chocolate agar; o Media for the selective isolation of pathogenic Neisseria; o Other media not listed on Table 3; o Media used for the isolation of parasites, viruses, mycoplasmas, chlamydia; o Muller Hinton media used for antimicrobial susceptibility tests; or o Media commercially prepared and packaged as a unit or system consisting of two or more different substrates, primarily used for microbial identification. Although Campylobacter medium, chocolate agar and media for the selective isolation of pathogenic Neisseria are listed on Table 3, these media must be retested by the user laboratory because these media have demonstrated higher failure rates. American Type Culture Collection (ATCC) control organisms are not necessarily required. However, if the laboratory uses "in-house" isolates for control organisms, it must have established reactivity for each organism. (Use D4149) Central laboratories that prepare media for satellite locations must either perform the same quality control checks required of commercial manufacturers listed on Table 3 of the National Committee for Clinical Laboratory Standards (NCCLS) Approved Standard (M22-A) and furnish documentation of media quality control checks to each satellite location, or each laboratory must continue to perform media checks as required under §493.1218(f). In accordance with §493.1213(b)(2), a laboratory's method verification of microbiology procedures is expected to demonstrate its ability to accurately and reliably isolate and/or identify each organism that the laboratory claims to be capable of isolating and/or identifying. Susceptibility testing procedures are verified according to the guidelines published by NCCLS. Commercial test systems including those for biochemical identification, antigen and antibody detection, and nucleic acid detection should be verified by using control organisms that verify the qualitative and quantitative performance claims of the manufacturer in accordance with the applicable requirements at §493.1218, Standard; Control procedures. (Use D4074-D4081, as applicable.) NOTE: In accordance with §493.1213(a), these requirements are not retroactive and do not apply to test methods in use prior to September 1, 1992, and also are not applicable to tests that meet the requirements of §493.1202(c).

TABLE 3
Control Microorganisms for Quality Assurance Testing of Commercially Prepared Media

Medium	Atmosphere, Length of Incubation	Control Organisms (ATCC)*	Expected Results
Anaerobic blood agars	Anaerobic, 24 to 48 h**	*B. fragilis* (25285) *C. perfringens* (13124) *F. nucleatum* (25586) *B. levil* (29147) *P. aneroblus* (27337)	Growth Growth, beta hemolysis Growth Growth Growth
Anaeitobic broths (thloglycollate medium, with or without indicator)	Aerobic, 48 h (lightened cap)	*C. novyl A* (7659) *S. sreus* (25923)	Growth Growth
(thlogycollate medium, enriched)		*B. levil* (29147) *B. vulgatus* (6482) *C. perfringens* (13124)	Growth Growth Growth
Nonselective sheep blood Agars	Aerobic or CO_2 24 h	*S. paganize* (19615) *S. pneumoniae* (6305) *S. aureus* (25923) *E. coli* (25922)	Growth, beta hemolysis Growth, alpha hemolysis Growth Growth
Camp Test TSA only***	Aerobic, 18-24 h	*S. aureus* (33862) *S. agafactise* (12386) *S. paganize* (19615)	Positive reaction (arrowhead area of clearing) Negative reaction (no arrowhead formation)
Selective sheep blood agars (Columbia CNA agar phenylethyl alcohol agar)	CO_2 24 h	*S. paganize* (19615) *S. pneumoniae* (6305) *S. aureus* (25923) *P. mirabllis* (12453)	Growth, beta hemolysis Growth, alpha hemolysis Growth Inhibition (partial)

Media for blood culture (Standard and poprietary formulation)	Anaerobic (nonvented) within 5 days	*S. pneumoniae* (6305) *B. fragille* (25285)	Growth Growth
	Aerobic (vented) within 5 days	*P. aeruginosa* (27853) *S. pneumoniae* (6305)	Growth Growth
Campylobacter agar	Reduced 0_2 ; 42°C, 48 h	*C. jenjui* (33281) *E. colt* (25922)	Growth Inhibition (partial)
Chocolate agar	CO_2 ; 8-24 h	*H. gonnorrhoeae* (43069) *H. Influenza* (10211)	Growth Growth
CIN	Aerobic, 24-48 h 25° C	Y. *enterocolitlca* (9610) *E. colt* (25922) *P. miravills* (12453) *P. seruginoza* (27852) *E. fascalis* (28212)	Growth; deep red center bulls eye; transparent border Inhibition (partial to complete) Inhibition (partial to complete) Inhibition (partial to complete) Inhibition (partial to complete)
CLED	Aerobic, 24-48 h 35° C	*E. colt* (25922) *P. vulgaris* (8427) *S. aureus* (25923)	Growth; yellow-deep yellow centers Growth; bluish, spreading Inhibited (Partial to complete at 24 h In areas of isolated colonies Growth; uniform deep yellow
CYE/BCYE	Aerobic, 48-72 h 35° C	*L. pneumophila* (33152) *L. Boxemanii* (33217)	Growth; fluoresces yellow-green under long wave u.v. light growth; fluoresces blue-white under long wave u.v. light

Enrichment broths for enterics (GN broth, Selenlte broth)	Aerobic, 24 h	*S. typhimurium* (14028) *S. sonnel* (9290) *E. coli* (25922)	Growth on subculture Growth on subculture (may be inhibited on Selenite Inhibition (partial to complete) on subculture. Growth on subculture from GN broth
Eosin methylene blue agars (Levine EMB agar, EMB agar, modified)	Aerobic, 24 h	*E. coli* (25922) *S. typhimurium* (14028) *E. faecalis* (29212)	Growth, blue-black colonies with green metallic sheen Growth, colorless to amber colonies Inhibition (partial)
MacConkey agar	Aerobic, 24 h	*E. coli* (25922) *P. mirabilis* (12453) *S. typhimurium* (14028) *E. faecalis* (29212)	Growth, pink colonies Growth, colorless colonies, Inhibition of swarming Growth, colorless colonies Inhibition (partial)
Mannltol salt agar	Aerobic, 24 and 48 h	*S. aureus* (25923) *S. epidermidis* (12228) *P. mirabilis* (12453)	Growth, colonies have yellow zones at 48 h *Growth, colonies have red zones at 48 h* Inhibition (partial)
Media for mycobacteria (L-J medium, Middlebrook media) excludes ATS	CO_2, up to 21 days	*M. tuberculosis* H37Ra (25177) *M. kansasil* Group I (12478) *M. scrofulaceum* Group II (19981) *M. Intracellulare* Group III (13950) *M. fortuitum* Group IV (6841) *E. coli* (25922)	Growth Growth Growth Growth - not included when testing selective L-J and selective Middlebrook media containing Penicillin or Carbenicillin. Growth Inhibition (partial to complete) 0 use only for selective mycobacteria media

Selective primary Isolation mycology agars; nutrient media containing cyclohezimide and chloramphenicol excluding Innhibitory mold agar	Aerobic, up to 7 days, 25° C	*A. niger* (16404) *C. albicans* (10231) *T. mentagrophytes* (9533) *E. coli* (25922)	Inhibition (partial to complete) (media containing cycloheximide) Growth Growth Inhibition (partial to complete) (media containing chloramphenicol)
Selective media for pathogenic Noisseria	CO_2, 24 to 48 h	*N. menigitidis* (13090)**** *N. gonorrhoeae* (43069) *P. mirabilis* (43071; not used to test Thayer-Martin agar. To be used with other media containing trimethoprim lactate to reduce growth and swarming of Proteus) *E. coli* (25922)**** *N. sicca* (9913)**** *C. albicans* (60193)**** *S. epidermidis* (12228)	Growth Growth Inhibition (partial) Inhibition (partial) Inhibition (complete) Inhibition (partial) Inhibition (partial)
Saboraud dextrose agar	Aerobic, up to 7 days 25-30° C	*C. albicans* (60193) *T. mentagrophytes* (9533)	Growth Growth
Media for Salmonella/ Shigella Hektoen enteric agar	Aerobic, 24 h	*S. typhimurium* (14028) *S. flexneri* (12022) *E. faecalis* (29212) *E. coli* (25922)	Growth, colonies blue to green-blue with black centers Growth, colonies green to blue-green Inhibition (partial; colonies yellow) Inhibition (partial to complete; colonies yellow to salmon colored)

XLD agar		*S. typhimurium* (14028) *S. flexnrel* (12022) *E. faecalis* (29212) *E. coli* (25922)	Growth, colonies red with black centers Growth, colonies red Inhibition (partial) Inhibition (partial to complete; colonies yellow to yellow-red)
S-S agar		*S. typhimurium* (14028) *S. flexnrel* (12022) *E. faecalis* (29212) *E. coli* (25922)	Growth, colonies colorless with or without black centers Growth, colorless colonies Inhibition (complete) Inhibition (partial to complete; colonies pink to rose-red with precipitate)
Selective media for group D streptococci Including BEA with azide	Aerobic, 24 and 48 h	*E. faecalis* (29212) *S. paganize* (19615) *E. coli* (25922)	Growth, blackening around colonies Inhibition (partial to complete) Inhibition (partial) colorless colonies
Differential media for group D streptococci Including BEA without azide	Aerobic, 24 and 48 h	*E. faecalis* (29212) *S. paganize* (19615)	Growth, blackening around colonies Inhibition (partial to complete)
General purpose tubed media (BHI and T. Soy)	Aerobic, 24-48 h	*E. coli* (25922) *S. aureus* (25923)	Growth Growth

*ATCC is a registered trademark of the American Type Culture Collection.

**The recommended duration of incubation for all media listed in Table 3 is not intended as a recommendation for maximum incubation time of clinical specimens. Media may be incubated for greater lengths if time in actual clinical use.

***Performed on each lot of dehydrated basal medium.

****To be used only by commercial manufacturers.

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D4188	**§493.1227 Condition: Bacteriology.** To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 and with paragraphs (a) through (c) of this section.	§493.1227 Guidelines: For all devices, products, or test systems cleared or approved by the FDA as moderately complex and have not been modified by the laboratory, cite QC record keeping deficiencies at D6072. All other QC record keeping deficiencies should be cited at D4182. For FDA cleared or approved moderately complex culture and non-culture, i.e., direct antigen, identification systems that have not been modified by the laboratory, the laboratory must meet §493.1202(c). For all other non-culture identification systems, laboratories may use bacterial cell suspensions to meet the requirement for control organisms since the cell suspensions are subjected to both the extraction and reaction phases of the test. However, a matrix similar to patient specimens is preferred. For example, ready prepared, dried (solid-shafted) swabs, one containing Group A Streptococcus as a positive control and another with non-Group A Streptococcus and/or Staphylococcus aureus as a negative control may be used. (Use D4140 and/or D4142, as appropriate.) For all tests excluding products cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, in accordance with §493.1218(f)(1), for microbial identification systems utilizing two or more substrates, the laboratory must check each media using control organisms to verify positive and negative reactivity. (Use D4151.) §493.1227(a)(1) Guidelines: For anaerobic bacteriology, the catalase reagent need only be checked with a control organism that produces a positive reaction. §493.1227(a)(3) Guideline: In addition to Salmonella and Shigella antisera, antisera used for serotyping of homologous isolates, e.g., streptococcal serotyping systems, must be checked for positive and negative reactivity. Polyvalent antisera should be tested with at least one organism from each polyvalent group. Antisera used in aerobic culture identification that will directly impact on patient care, i.e., Salmonella and Shigella, should be quality controlled with the opening of each new vial (Use D4151) and at least monthly thereafter using an organism that produces a positive reaction and an organism that produces a negative reaction. (Use D4205.) EXCEPTION: Antisera used for epidemiological categorization following routine testing should be tested using control strains with the opening of each new vial and quarterly. §493.1227(c)(1)-(2) Guidelines: "Approved reference organism(s)" means either an appropriate control strain or an equivalent strain as defined below.
	All quality control activities must be documented.	
D4193	(a) The laboratory must check positive and negative reactivity with control organisms-- (1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;	
D4199	(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and	
D4205	(3) Each month of use for antisera.	
D4206	(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.	
D4208	(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4212	(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.	**ANTIMICROBIAL DISC DIFFUSION SUSCEPTIBILITY (BAUER, KIRBY, SHERRIS AND TURK METHOD)** Each new batch of medium and each new lot of antimicrobial discs must be checked as follows: ANTIMICROBIAL DISC SUSCEPTIBILITY TEST Appropriate control strain / Each new batch of media and discs / Each day if isolates are: S.aureus ATCC 25923 or equivalent** — X — Gram + E. coli ATCC 25922 or equivalent** — X — Enteric P. aeruginosa ATCC 27853 or equivalent** — X — Pseudomonas species E. faecalis ATCC 29212 or equivalent** — When trimethoprim-sulfamethoxazole is included as an antibiotic — N/A Zone sizes must be recorded for each antimicrobial control and limits must be established. **An equivalent strain is one which demonstrates reactivity similar to an ATCC strain and for which limits have been established. Organisms which manufacturers recommend or require for use in their systems are acceptable strains of control organisms. EXCEPTION: The laboratory may test each appropriate control strain a minimum of once each week that patients are tested, provided the following requirements are met: The laboratory must document that appropriate control strains were tested for a minimum of thirty (30) consecutive test days. For each drug-microorganism, no more than three of the 30 zone diameters (i.e., zone diameters obtained from one drug-microorganism combination for 30 consecutive test days), may be outside established accuracy control limits. These limits may be established by the laboratory, or the laboratory may use the accuracy control limits provided in Table 3*** of the National Committee for Clinical Laboratory Standards (NCCLS) Approved Standard, Performance Standards for Antimicrobial Disc Susceptibility Tests, Fourth Edition. NOTE: This procedure is to be used only for establishing satisfactory performance of the disk diffusion tests through performance of quality control tests weekly instead of daily. Do not confuse this procedure with the steps that must be taken for corrective action.
D4213	(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.	

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		In addition, for each drug-microorganism combination, none of the six (6) zone ranges (obtained from grouping the 30 control test results in 6 groups of 5 consecutive tests each) may be greater than the maximum allowable range for precision established by the laboratory or the range listed in Table 4*** of the NCCLS Approved Standard, Performance Standards for Antimicrobial Disc Susceptibility Tests, Fourth Edition. *Permission to reproduce Tables 3 and 4 from M2-A4 "Performance Standards for Antimicrobial Disk Susceptibility Test", Fourth Edition; and Approved Standard and Table 3 from M7-A2 "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically" --Second Edition, Approved Standard, has been granted by NCCLS. Copies of each of these complete current standards may be obtained from NCCLS, 771 E. Lancaster Avenue, Villanova, Pennsylvania 19085. Generally, one out of every 20 tests in a series of tests might be out-of-control (i.e., outside the stated accuracy control limits). Two consecutive tests out-of-control, or any more than two out-of-control results in 20 consecutive control tests requires corrective action. However, one zone diameter beyond four standard deviations above or below the midpoint between the stated limits, i.e., midpoint +/- the stated accuracy range (maximum minus minimum zone diameter) also requires corrective action. ANY TIME corrective action is taken, the count of 20 begins again. NOTE: Do not confuse this procedure with those procedures used for establishing satisfactory performance of the disk diffusion tests through the performance of quality control tests weekly instead of daily. NOTE: The maximum zone range (largest minus smallest zone diameter in a group of five consecutive control test results) observed in a series of five consecutive control test results should not exceed the maximum allowable range listed in Table 4 of the NCCLS Approved Standard, Performance Standard for Antimicrobial Disc Susceptibility Tests or limits established by the laboratory. If a zone diameter is observed outside the established accuracy control limits during weekly quality control testing, the following control checks are necessary: o Appropriate control strain(s) must be tested for five (5) consecutive days; o For each drug-microorganism combination, all of the above five (5) zone diameters must be within established accuracy control limits; and o The zone range of the five (5) consecutive control tests for each drug-microorganism combination may not be greater than the established range for precision. If either of the last two items mentioned above occurs (i.e., at least one zone diameter is observed outside the accuracy control limits or the zone range is larger than the maximum allowable range for precision), the laboratory must continue daily control testing for a minimum of another 30 consecutive days. It must also meet the accuracy and precision requirements for daily quality control.

TABLE 3 Control Limits for Monitoring Antimicrobial Disk Susceptibility Tests - Zone Diameter (mm) Limits for Individual Tests on Mueller-Hinton Medium Without Blood or Other Supplements

Antimicrobial Agent	Disc Content	*E. coli* (ATCC® 25922)	*S. aureus* (ATCC® 25923)	*P. aeruginosa* (ATCC® 27583)	*E. coli* (ATCC® 35218)
Amikacin	30 pg	19-26	20-26	18-26	---
Amoxicillin/ Clavulanic Acid	20-10 pg	19-25	28-36	---	18-22
Ampicillin	10 pg	16-22	27-35	---	---
Ampicillin/Sulbactam	10-10 pg	20-24	29-37	---	13-19
Azlthrimycin	15 pg	---	21-26	24-30	---
Azlocillin	75 pg	---	---		---
Aztreonam	30 pg	28-36	---	23-29	---
Carbenicillin	100 pg	23-29	---	18-24	---
Cafaclor	30 pg	23-27	27-31	---	---
Cefamandole	30 pg	26-32	26-34	---	---
Cefazolin	30 pg	23-29	29-34	---	---
Cefixime	5 pg	23-27	---	---	---
Cefmetazole	30 pg	26-32	25-34	---	---
Cefodicid	30 pg	25-29	22-28	---	---
Cefoperazone	75 pg	28-34	24-33	23-29	---
Cefotaxime	30 pg	29-35	29-35	18-22	---
Cefotetan	30 pg	28-34	17-23	---	---
Cefoxilin	30 pg	23-29	23-39	---	---
Ceftaxideime	30 pg	25-32	16-20	22-29	---
Ceftizoxime	30 pg	30-36	27-35	12-17	---
Ceftrizxone	30 pg	29-35	22-28	17-23	---
Cefuuroxime	30 pg	20-26	27-35	---	---
Cephalothin	30 pg	15-21	29-37	---	---
Chloramphenicol	30 pg	21-27	19-26	---	---
Cinoxacin	100 pg	26-32	---	---	---
Ciprofloxacin	5 pg	30-40	22-30	25-33	---
Clarithromycin	15 pg	---	26-32	---	---
Clindamycin	2 pg	---	24-30	---	---
Doxycycline	30 pg	18-24	23-29	---	---
Enoxacin	10 pg	28-36	22-28	22-28	---
Erythromycin	15 pg	---	22-30	---	---
Gentamicin	10 pg	19-26	19-27	16-21	---

Imipenem	10 pg	26-32	---	20-28	---
Kanamycin	30 pg	17-25	19-26	---	---
Lomefloxacin	10 pg	27-33	23-29	22-28	---
Loracarbel	30 pg	23-29	23-31	---	---
Methicillin	5 pg	---	17-??	---	---
Mezlocillin	75 pg	23-29	---	19-25	---
Minocycline	30 pg	19-25	25-30	---	---
Moxalactam	30 pg	28-35	18-24	17-25	---
Nafcillin	1 pg	---	16-22	---	---
Nalidixic Acid	30 pg	22-28	---	---	---
Netilmicin	30 pg	22-30	22-31	17-23	---
Nitrofurantoin	300 pg	20-25	18-22	---	---
Norfloxacin	10 pg	28-35	17-28	22-29	---
Ofloxacin	5 pg	29-33	24-28	17-21	---
Oxacillin	1 pg	---	18-24	---	---
Penicillin G	10 units	---	26-37	---	---
Piperacillin	100 pg	24-30	---	25-33	---
Rifampin	5	8-10	26-34	---	---
Streptomycin	10 pg	12-20	14-22	---	---
Sulfisoxazole	250 pg or 300 pg	18-26	24-34	---	---
Telcoplanin	30 pg	---	15-21	---	---
Temafloxacin	5 pg	28-34	25-31	19-24	---
Tetracycline	30 pg	18-25	19-28	---	---
Ticarcillin	75 pg	24-30	---	22-28	---
Ticarcillin/Clavulanic	75-10 pg	25-29	---	20-28	21-25
Acid	10 pg	18-26	19-29	19-25	---
Tobramycin	5 pg	21-28	19-26	---	---
Trimethoprim				---	---
Trimethropim/	1.25/23.75 pg	24-32	24-32	---	---
Sulfamethoxazole	30 pg	---	15-19	---	
Vancomycin					

NOTE 1: To determine whether the Mueller-Hinton mum has sufficiently low levels of thymine, an *E. faecalis* (ATCC 29212 or 33186) may be tested with trimethoprim/sulfamethoxazole
disks. An inhibition zone of $\geq$ 20 mm which is essentially free of line colonies indicates a sufficiently low level of thymine and thymidine. [See sections 3.1.2 and 4.3.1(9)]
NOTE 2: Information in boldface type is considered tentative for one year.
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TABLE 3 Maximum Zone Diameter Range That Should be Observed in a Series of Five Consecutive Control Test Results

Antimicrobial Agent	Disk Content	*E. coli* (ATCC® 25922)	*S. aureus* (ATCC® 25923)	*P. aeruginosa* (ATCC® 27853)	*E. coli* (ATCC® 35218)
Amikacin	30 pg	6	6	6	---
Amoxicillin/Clavulanic	20/10 pg	7	9	---	4
Acid	10 pg	6	8	---	---
Ampicillin	10/10 pg	4	9	---	7
Ampicillin/Sulbactam	15 pg	---	4	---	---
Azithromycin	75 pg	---	---	8	---
Azlocillin					
Aztreonam	30 pg	10	---	10	---
Carbenicillin	100 pg	10	---	8	---
Cefactor	30 pg	4	4	---	---
Cefamandole	30 pg	8	8	---	---
Cefazolin	30 pg	8	8	---	---
Cefixime	5 pg	4	---	---	---
Celmetazole	30 pg	7	---	---	---
Cefonicid	30 pg	8	4	---	---
Cefoperazone	75 pg	10	8	---	---
Cefotaxime	30 pg	10	8	---	---
Cefotetan	30 pg	8	---	---	---
Cefozitin	30 pg	8	7	---	---
Ceftazidime	30 pg	8	8	8	---
Ceftizoxime	30 pg	10	10	8	---
Ceftnaxone	30 pg	10	10	10	---
Cefuroxime	30 pg	8	8	---	---
Cehalothin	30 pg	8	8	---	---
Chloramphenicol	30 pg	10	10	---	---
Cinozacin	100 pg	9	---	---	---
Ciprofloxacin	5 pg	9	7	7	
Clindamycin	2 pg	---	6	---	---
Doxycline	30 pg	8	8	---	---
Enoxacin	10 pg	9	7	7	---
Erythromycin	15 pg	---	9	---	---
Gentamicin	10 pg	6	6	6	---
Imipenem	10 pg	6	---	6	---
Kanamycin	30 pg	9	9	---	---

Lomefloxacin	10 pg	7	7	7	---
Loracarbel	30 pg	7	7	---	---
Methicillin	5 pg	---	9	---	---
Mezlocillin	75 pg	8	---	8	---
Minocycline	30 pg	9	9	---	---
Moxalaciam	30 pg	10	10	10	---
Nafcillin	1 pg	---	6	---	---
Malidixie Acid	30 pg	10	---	---	---
Netilmicin	30 pg	6	6	6	---
Nitrofurantoin	300 pg	6	6	---	---
Norfloxacin	10 pg	9	9	9	---
Ofloxacin	5 pg	7	7	7	---
Oxacillin	1 pg	---	6	---	---
Penicillin **G**	10 pg	---	8	---	---
Piperacillin	100 pg	8	---	8	---
Streptomycin	10 pg	8	8	---	---
Sulfisoxazole	250 pg or 300 pg	9	9	---	---
Telcoplanin	30 pg	---	4	---	---
Temafloxacin	5 pg	7	7	6	---
Tetracycline	30 pg	9	9	---	---
Ticarcillin	75 pg	8	---	8	---
Ticarcillin/ Clavulanic Acid	75-10 pg	7	9	4	9
Tobramycin	10 pg	6	6	6	---
Trimethorpin	5 pg	10	10	---	---
Trimethorpin/ Sulfamethoxazole	1.25/23.75 pg	10	10	---	---
Vancomycin	30 pg	---	6	---	---

NOTE 1: Zone Diameter Range is defined as the largest minus the smallest zone diameter in a group of five consecutive control test results. limits indicates that precision is sufficient to ensure that the probability of major interpretative error (RS S) is less than 1%.

NOTE 2: Maximum zone diameter ranges have been calculated using formulae for determining control charts for ranges (ASTM Manual on Quality Control of Materials, Special Technical Publication 15-C, American Society for Testing and Materials, Philadelphia, Pennsylvania, 1951). Performance within these considered tentative for one year.

NOTE 3: Information in boldlace type is

TABLE 3 Acceptable Quality Control Ranges of MICs (pg/mL) for Reference Strains

Antimicrobial Agent	*S. aureus* ATCC 29213	*E. faecalis* ATCC 29212	*E. coli* ATCC 27853	*P. aeruginosa* ATCC 27853	*E. coli* ATCC 35218
Amikacin	1-4	64-256	0.5-4	0.5-8	---
Amoxicillin/Clavulanic	---	---	2/1-8/4	---	4/2-16/8
Acid	0.25-1	0.5-2	2-8	---	---
Ampicillin	---	---	1/0.5-4/2	---	4/2-16/8
Ampicillin/Sulbactam	0.25-1	---	---	---	---
Azitromycin	2-8	1-4	8-32	2-8	---
Azlocillin	---	---	0.06-0.25	2-8	---
Aztreonam					
Carbenicillin	2-8	16-64	4-16	16-64	---
Cafactor	1-4	>32	1-4	---	---
Cefamandole	0.25-1	16-64	0.25-1	---	---
Cefazolin	0.25-1	>16	1-4	---	---
Cefixime	8-32	≥32	0.25-1	---	---
Celmetazole	0.5-2	≥32	0.25-2 [a]	>32	---
Cefonicid	1-4	---	0.25-1	---	---
Cefoperazone	1-4	8-32	0.12-0.5	2-8	---
Cefataxime	1-4	>32	0.06-0.25	4-16	---
Cefotetan	4-16	>32	0.06-0.25	---	---
Cefoxitin	1-4	>128	1-4	---	---
Ceftazidime	4-16	---	0.06-0.5 [a]	1-4	---
Ceftizoxime	2-8	---	0.03-0.12	16-64	---
Ceftriaxone	1-8 [a]	---	0.06-0.12	8-32	---
Cefuroxime	0.5-2	---	2-8	---	---
Cephalothin	0.12-0.5	8-32	4-16	---	---
Chloramphenicol	2-8	4-16	2-8	---	---
Cinoxacin	---	---	2-8	---	---
Ciprofloxacin	0.12-0.5	0.25-2 [a]	0.004-0.015	0.25-1	---
Clarithomycin	0.12-0.5	---	---	---	---
Clindamycin	0.06-0.25	4-16	---	---	---
Enoxacin	0.5-2	2-16	0.06-0.25	2-8	---
Erythromycin	0.12-0.5	1-4	---	---	---
Gentamicin	0.12-1 [a]	4-16	0.25-1	0.25-4	---
Imipenem	0.015-0.06	0.5-2	0.06-0.25	1-4	---
Kanamycin	1-4	16-64	1-4	---	---

Lomefloxacin	0.25-2	2-8	0.03-0.12	1-4	---
Loracarbel	0.5-2	>8	0.5-2	>8	---
Methicillin	0.5-2	>16	---	---	---
Mezlocillin	1-4	1-4	2-8	8-32	---
Minocycline	0.12-0.5	2-8	0.5-2	---	---
Moxalactam	4-16	>128	0.12-0.5	8-32	---
Nafcillin	0.12-0.5	2-8	---	---	---
Netilmicin	≤0.25	4-16	≤0.5-1	0.5-8	---
Oxacillin	0.12-0.5	8-32	---	---	---
Ofloxacin	0.12-1 [a]	1-4	0.15-0.12 [a]	1-8 [a]	---
Penicillin G	0.25-1	1-4	---	---	---
Piperacillin	1-4	1-4	1-4	1-4	---
Piperacillin/Tazobactam	1.0/0.12-4.0-0.5	2.0/0.25-8.0/1	1.0/0.12-4.0/0.5	2.0/0.25-8.0/1	2.0/0.25-8.0-1
Rifampim	0.008-0.06	1-4	8-32	32-64	---
Telcoplanin	0.25-1.0	0.06-0.25	---	---	---
Temafloxacin	0.06-0.25	0.5-2.0	0.016-0.06	1-4	---
Tetracycline	0.25-1	8-32	1-4	8-32	---
Ticarcillin	2-8	16-64	2-8	8-32	---
Ticarcillin/Claculanic Acid	0.5/2-2/2	16/2-64/2	2/2-8/2	8/2-32/2	4/2-16/2
Tobramycin	0.12-1	8-32	0.25-1	0.12-2	---
Vancomycin	0.5-2	1-4	---	---	---
Nalidixic Acid	---	---	1-4	---	---
Nitrofurantoin	8-32	4-16	4-16	---	---
Norfloxacin	0.5-2	2-8	0.06-0.12	1-4	---
Sulfisoxazole [b]	32-128	32-128	8-32	---	---
Trimethoprim [b]	1-4	≤1	0.5-2	>64	---
Trimethoprim/ Sulfamethoxazole (1/19) [b]	≤0.5/9.5	≤0.5/9.5	≤0.5/9.5	8/152-32/608	---

NOTE 1: These MICs obtained in several reference laboratories by broth microdilution. If four or fewer concentrations are tested, quality control may be more difficult (see Section 1.3).
NOTE 2: Information in boldface type is considered **tentative** for one year.

FOOTNOTES

a. A bimodal distribution of MICs, results at the extremes of the acceptable range should suspect. Verify control validity with data from other control strains.
b. Very medium-dependent, especially with enterococci.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS

MINIMUM INHIBITORY CONCENTRATION (MIC)
Each new batch of macrodilution tubes, microdilution trays, or agar dilution plates must be checked as follows:

	MINIMUM INHIBITORY CONCENTRATION (MIC)	
Appropriate control strain	Each new batch of media	Each day if isolates are
S.aureus ATCC 29213 or equivalent	X	Gram +
E.coli ATCC 25922 or equivalent	X	Enteric
P. aeruginosa ATCC 27853 or equivalent	X	Pseudomonas species
E. faecalis ATCC 29212 or equivalent	When trimethoprim-sulfamethoxazole is included as an antibiotic	N/A

Each day the test is performed, the appropriate control strain(s) must be included to check the test system.

EXCEPTION: The laboratory may test each appropriate control strain(s) a minimum of once each test week if the following requirements are met:

The laboratory must document that appropriate control strains are tested for a minimum of thirty (30) consecutive test days. For each drug-microorganism, no more than three of the MIC values (i.e., MIC values obtained from one drug-microorganism combination for 30 consecutive test days) may be outside established accuracy control limits. (These limits may be established by the laboratory or the laboratory may use the accuracy limits provided in Table 3 of the NCCLS Approved Standard, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically.)

NOTE: This procedure is to be used only for establishing satisfactory performance of the MIC tests through the performance of quality control tests weekly instead of daily.

Generally, one out of every 20 tests in a series of tests might be out-of-control (i.e., outside the stated accuracy control limits). Two consecutive tests out-of-control,or any more than two out-of-control results in 20 consecutive control tests requires corrective action. Any time corrective action is taken, the count of 20 begins again.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		NOTE: Do not confuse this procedure with those procedures used for establishing satisfactory performance of the MIC tests through the performance of quality control tests weekly instead of daily. Whenever an MIC value is observed outside the established accuracy control limits during weekly quality control testing, the following control checks are required: o Appropriate control strain(s) must be tested for five (5) consecutive days; and o For each drug-microorganism combination, all of the above five (5) MIC values must be within established accuracy control limits. If at least one MIC value is observed outside the accuracy control limits for each drug-microorganism combination, the laboratory must continue daily control testing for a minimum of another 30 consecutive days. It must also meet the accuracy requirements for daily quality control. Automated equipment using an algorithm system to determine antibiotic susceptibility qualifies for testing each appropriate control organism once each week, if the above requirements are met. Laboratories performing manual breakpoint susceptibility testing do not qualify for the NCCLS exception for weekly quality control, and therefore must perform quality control using appropriate organisms each day of use. §493.1227(c)(1)-(2) Probes: How does the laboratory ensure proper standardization of the inoculum, e.g., 0.5 MacFarland standard? (Use D4110.)
D4215	**§493.1229 Condition: Mycobacteriology.** To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1229 Probes: How often are mycobacteriology cultures checked for growth prior to the issuance of final patient reports? How long are negative cultures held before a final patient report is issued, i.e., minimum of six weeks? (Use D4022 or D4023, as applicable.) For all devices, products, or test systems cleared or approved by the FDA as moderately complex and have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. All other QC recordkeeping deficiencies should be cited at D4182.
	All quality control activities must be documented.	
D4217	(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and wth an organism that produces a negative reaction	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4220	and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.	§493.1229(d) Guidelines: A susceptible control strain of Mycobacterium tuberculosis, such as H37Rv or other appropriate control strain, must be used to check the susceptibility procedure.
D4221	(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.	
D4224	(c) The laboratory must check acid-fast stains each week of use with an acid-fast organism that produces a positive reaction.	
D4226	(d) For susceptibility tests performed on Mycobacterium tuberculosis isolates, the laboratory must check the procedure each week of use with a strain of Mycobacterium tuberculosis susceptible to all antimycobacterial agents tested.	
D4228	**§493.1231 Condition: Mycology.** To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1231 Guidelines: For FDA cleared or approved moderately complex non-culture, i.e., direct antigen test systems that have not been modified by the laboratory, the laboratory must follow 493.1202(c). For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182.
	All quality control activities must be documented.	
D4230	(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.	
D4232	(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.	§493.1231(b) Guideline: Reagents and test procedures used for identification purposes may include, but are not limited to, germ tube, yeast morphology media, and commercial identification systems. A negative reactivity control is not required for the mycology germ tube test. §493.1231(b) Probe: What tests and test procedures are used to identify mycology organisms and how does the laboratory determine that these procedures provide accurate results? (Use D4022 or D4023, as applicable.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4235	(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.	§493.1231(d) Probe: Which control strains are used and how did the laboratory establish acceptable control limits for susceptibility tests?
D4238	(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug.	
D4240	The laboratory must establish control limits.	
D4241	Criteria for acceptable control results must be met prior to reporting patient results.	
D4242	**§493.1233 Condition: Parasitology.** To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.	§493.1233 Guidelines: For FDA cleared or approved moderately complex non-culture, i.e., direct antigen test systems that have not been modified by the laboratory, the laboratory must follow §493.1202(c). For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. §493.1233 Probes: If the laboratory uses zinc sulfate for concentration of fecal specimens for ova and parasite examination, what is the specific gravity of the zinc sulfate solution? (The acceptable specific gravity is 1.18 for fresh fecal samples and 1.20 for formalinized fecal samples.) (Use D4022 or D4023, as applicable.) §493.1233(a) Guideline: The laboratory must have adequate reference material, but does not have to maintain several different reference systems. Textbooks with photographs, previously stained slide preparations, preserved specimens, or slides from proficiency testing programs are some acceptable systems. §493.1233(b) Guideline: Check for the following: o Instructions for calibration (use D4052); o Figures to show each objective (high, oil, low) has been calibrated; o Presence of an ocular micrometer for the microscope(s) used; and o Criteria for the use of the micrometer for determining the size of ova and parasites (use D4050). §493.1233(b) Probe: How has the laboratory determined the accuracy of the ocular calibration and that the staff has the knowledge for proper use?
	All quality control activities must be documented.	
D4244	(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.	
D4246	(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4248	(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.	§493.1233(c) Guidelines: While a wet mount preparation may not be sufficiently sensitive to detect small numbers of ova or parasites in fecal specimens, or to render a final species identification, the regulations do not require use of concentrated and permanent stain techniques to identify fecal parasites. It is the laboratory's responsibility to assure that it can accurately and reliably identify the organisms it claims to be able to identify (use D4022 or D4023, as applicable), and, upon request, to specify the method employed by the laboratory for screening fecal specimens and to provide information to clients on the test report that may affect the interpretation of test results. (Use D3067-D3069, D6061, or D6139 as applicable.) The fecal sample control may contain either parasites or added leukocytes sufficient to demonstrate staining characteristics. §493.1233(c) Probes: The working iodine solution is stable for approximately two weeks. If the laboratory does not prepare fresh working iodine solution at least every two weeks, how does it assure that the iodine solution being used has not deteriorated? (Use 493.1205(e)(1).)
D4250	**§493.1235 Condition: Virology.** To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.	§493.1235 Guidelines: For commercially purchased cell culture media, the requirement for media quality control checks is satisfied by visually examining the media for sterility and assuring the ability of the media to sustain cell life. If the media is prepared or produced in the laboratory: o Each component of cell culture media should be checked for sterility using bacterial culture techniques. (Use D4159.) In addition, fetal bovine serum must be checked for toxicity using cell culture systems (use D4160.); o The combined product (e.g., Hanks, Eagles and Earles) should be checked for sterility using bacterial culture techniques and the ability to propagate growth with cell cultures (use D4159 and D4160, as approproate.); and o Cell culture systems should be checked for mycoplasma contamination at regular intervals established by the laboratory to prevent contamination.(Use D4159.) "493.1235(a)-(c) Guidelines: For FDA cleared or approved moderately complex non-culture, i.e., direct antigen test systems that have not been modified by the laboratory, the laboratory must follow 493.1202(c). For all other non-culture (direct antigen) systems that are used for viral identification, the laboratory is not required to maintain live viral cultures for quality control purposes. However, positive and negative controls are required to evaluate the detection phase, if such controls are available commercially or in the laboratory. (Use D4140.) If organism controls are not available, a previously extracted viral antigen as the positive control plus a previously confirmed negative control of the same matrix as the patient sample may be used. (Use D4144.) A positive organism control must be subjected
	All quality control activities must be documented.	
D4252	(a) The laboratory must have available host systems for the isolation of viruses	
D4253	and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.	
D4254	(b) The laboratory must maintain records that reflect the systems used and the reactions observed.	

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D4256	(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.	to the extraction process if such a control is available in the laboratory. (Use D4142.) For fluorescent stains, the control requirements are met by using virus-infected cells for a positive control among uninfected cells for a negative control. (Use D4156.) For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. The intent of the regulations at §493.1235(a) is for the laboratory to have methodologies available to isolate and identify the viruses it claims to be able to isolate and identify that are etiologically related to the clinical disease for which services are offered. (For example, if a laboratory offers services only for Herpes testing, it must have available host systems for the isolation and/or test methods for the identification of the Herpes virus.) "Host systems" is defined as the animal, egg or cell culture model which supports the propagation of viruses. Clinical information important for the determination and selection of the proper host system should include: (Use D3029.) o Clinical symptoms of the patient; o Age of the patient; o Source of the specimen; o Date of onset of clinical symptoms; o Recent travel information of patient; o Clinicians test request; and o Date of specimen collection. The cell culture host system is most frequently used. Generally, 2-4 uninoculated cell controls are used per inoculation day to determine whether the consequent cytopathic effect (CPE) in the cells inoculated with patient specimen was caused by specific etiologic agent(s), or caused by the nonspecific deterioration of the cells themselves. Often, as monolayer host cells age, the cells deteriorate, exhibiting "rounding" and "pulling-apart". This cell change may be confused with CPE if uninoculated cells are not available to compare with the inoculated cells. Uninoculated cell substrate controls are used to determine whether sensitivity and specificity of a test system have been assured, e.g., in test systems utilizing specific antibodies directed to a specific virus, the uninoculated cell substrate is used to determine that the reaction observed (whether fluorescence, agglutination, or lysis) is a result of the specific antibody-virus reaction and not a nonspecific binding of serum components and cell substrate.

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		The specific cell culture is usually selected based upon its known sensitivity and susceptibility to different viruses. For example, the cell cultures to be used as host systems for the following clinical specimens could be: o Upper respiratory infection specimens: Primary Monkey Kidney (PMK), Human Fetal Diploid Lung (HFDL), or equivalent; o Enteric specimens: PMK, Human Fetal Diploid Kidney (HFDK), or equivalent; o Urine specimens: HFDL, PMK, or equivalent; o Genital specimens: Human Foreskin (HFD), Vero, or equivalent; o Vesicular lesions: HFDL, PMK, BSC-1 (Monkey Cell Line), or equivalent; and o Tissues or Spinal fluids: PMK, Vero or BSC-1, HFDK or HFDL, or equivalent. Prior to the inoculation of the cell cultures, the laboratory should check the cell culture systems for the following: o The age of the cell culture monolayer (no more than 7-10 days post "seeding") (use D4038); o Maintenance media that is free from inhibitory substances (use D4160); and o Sterility (visual observation for turbidity.) (Use D4159.) "493.1235(a)-(c) Probes: How many tubes of the same batch of cell culture monolayers are maintained for the patient sample as uninoculated controls? (Use D4256.) When reviewing the laboratory's identification procedures for the clinical diseases for which services are offered, how does the laboratory rule out the presence of Clostridium difficile toxin in those cell cultures in which the patient specimen exhibits non-specific effects unrelated to viral cytopathic effect (CPE)? (Use D4253 or D4074.) If presumptive reports are issued based on CPE, how does the laboratory confirm the identification reported? (Use D4023, D4253, or D4074, as applicable.) How does the laboratory determine the specific cell culture to be used as the host system? (Use D4253.) For tests such as hemagglutination inhibition and viral neutralization in which antisera must be standardized, how has the laboratory determined the optimum dilution of the antisera to assure maximum sensitivity and specificity? (Use D4074.) Neutralization Tests: How does the laboratory standardize its dilution of the viral isolate and control virus to the appropriate Tissue Culture $Dose_{50}$ or equivalent, each time the test is performed? (Use D4110.) How many varieties of uninoculated cell cultures does the laboratory use to check each new lot of anti-serum or serum pool for toxicity? (Use D4160.)

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		Hemagglutination Inhibition Tests: After having determined the hemagglutination titer, how does the laboratory determine the working dilution of the viral isolate, i.e., usually 4 Hemagglutination units? How does the laboratory ensure that this working dilution is correct for isolates and controls? (Use D4074.) How many uninoculated cell controls (tubes or plates) does the laboratory use with each test? (Use D4132.) How often and for which hemagglutination inhibition tests does the laboratory include a serum/cell/buffer control and a cell/buffer control? (Use D4081.) Does the laboratory include one known virus or viral antigen specific to each antisera used in the test procedure? (Use D4132.) Direct Immunofluorescence Tests: How does the laboratory determine which immune serum conjugate(s) to use when identifying viruses using antisera that react with viruses that are etiologically similar, e.g., an antigen test for specimens from patients with flu-like symptoms that identifies Respiratory Syncytial Virus, Influenza, and Parainfluenza? How does the laboratory assure the specificity of this conjugate for the specific virus being identified? (Use D4074.) How does the laboratory rule out non-specific reactivity for each conjugate used? (Use D4074.) Indirect Immunofluorescence Tests: How does the laboratory determine the optimum dilution of its anti-species, e.g., antibody to host system or cell culture, e.g., anti-PMK, conjugated immune serum? (Use D4074.) How does the laboratory determine the optimum dilution of the virus specific immune serum? (Use D4074.) Determine whether the laboratory is checking positive and negative reactivity using o Uninoculated cells plus immune serum plus anti-species conjugate (negative control); and o Viral antigen or known virus infected cells plus immune serum plus anti-species conjugate (positive control) (Use D4156.) Determine whether the laboratory checks each new batch or shipment of conjugate using known virus infected cells plus PBS plus anti-species conjugate. (Use D4151.)

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		Do the laboratory's records identify the host cell cultures employed, the number of tubes or plates inoculated or uninoculated, maintenance medium used, the number of times the patient specimen was sub-cultured, the specific sub-culture or passage in which the virus was identified, the CPE observed, and post inoculation date of observations? (Use D4254. If the deficiency is due to absence of dates of testing and observations, use D3041.)
	§493.1237 Condition: Diagnostic immunology. The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.	
D4258	**§493.1239 Condition: Syphilis serology.** To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section.	§493.1239(a) Guidelines: Cite the deficiency under §493.1202(c) when using FDA cleared or approved products that are moderately complex that have not been modified by the laboratory, if the laboratory has failed to follow the instructions provided by the manufacturer for test parameters such as: o Antigen volume; o Incubation time and temperature; o Rotator speed and circumference; and o Conjugate titer. For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. §493.1239(b) Guidelines: For tests in which patient results are reported in terms of graded reactivity, e.g., 1+, 2+, minimally reactive, control(s) of graded reactivity must be used. For tests in which patient results are reported as a titer, controls of known titer must be used. §493.1239(c) Probes: For FTA-ABS tests, does the laboratory employ: o Reactive control serum in PBS; o Reactive control serum in sorbent; o Minimally reactive control 1+; o Non-specific serum control in PBS; o Non-specific serum control in sorbent; o Non-specific staining control of PBS; and o Non-specific staining control of sorbent?
	All quality control activities must be documented.	
D4260	(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.	
D4265	(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.	
D4267	(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.	

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D4269	(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.	For MHATP or HATTS tests, does the laboratory employ: o Reactive reference control material; o Non-reactive reference control material; o Unsensitized erythrocyte with each specimen; o Unsensitized erythrocyte with buffer; o Sensitized erythrocyte with buffer; o Unsensitized erythrocyte with each reactive control serum; and o Unsensitized erythrocyte with non-reactive control serum? §493.1239(e) Guideline: 21 CFR 640.5(a) states, "All units of blood must be tested by an acceptable serological test for syphilis
D4270	(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).	
D4271	**§493.1241 Condition: General immunology.** To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1241 Guidelines: For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. §493.1241(a) Guidelines: For all laboratories performing immunological tests subject to §493.1202(a) and (b), the laboratory may perform quality control at the frequency specified here or at the frequency specified in §493.1218(b)(1) provided the requirements of §§493.1218(b) and 493.1218(f)(1) are met. For FDA cleared or approved moderately complex qualitative tests that have not been modified by the laboratory, the laboratory may perform quality control at the frequency defined in §493.1202(c)(4), if each batch or shipment of reagents, when prepared or opened, is checked for positive and negative reactivity prior to, or concurrent with, use on patient specimens. In addition, for tests in which patient results are reported in terms of graded reactivity, e.g., 1+, 2+, minimally reactive, control(s) of graded reactivity must be used. For tests in which patient results are reported as a titer, controls of known titer must be used. Exceptions: A negative control is not required for anti-streptolysin O titer, anti-hyaluronidase titer tests. A positive control is not required for the cold agglutination test. For radial immuno-diffusion, one control or standard is required on each plate.
	All quality control activities must be documented.	
D4273	(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.	
D4275	(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.	

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D4276	(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.	§493.1241(b) Guidelines: For test systems other than FDA-cleared or approved moderately complex tests that have not been modified by the laboratory, determine which immunological methods are used by the laboratory and how the laboratory tests quality control materials to check each test component of the test system. Examples of test systems which have multiple components are: o Complement fixation (CF); o Hemagglutination inhibition (HAI); o Radioimmunoassay (RIA); o Enzyme immunoassay (EIA); o Indirect immunofluorescence (IFA); o Fluorescence Polarization Immunoassay (FPIA); o Radioimmunoprecipitin assay (RIPA);
D4277	(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet-- (1) The HIV testing requirements of 21 CFR 610.45; and	
D4278	(2) Hepatitis testing requirements of 21 CFR 610.40	
	§493.1243 Condition: Chemistry. The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.	
D4280	**§493.1245 Condition: Routine chemistry.** To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221.	§493.1245 Guidelines: Use §493.1202(c)(4) for FDA-cleared or approved, moderately complex urine microscopic test systems that have not been modified by the laboratory, when the laboratory fails to run a positive control each day of testing. Use D4135 for all other urine microscopic test systems/examinations when the laboratory fails to run a positive control with each run. A negative control is not required for urine microscopic test systems/examinations. For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. "493.1245(a)-(d) Guidelines: For blood gas analysis, all levels of test complexity as described in §§493.1202(a),(b), and (c) must perform calibration and calibration verification in accordance with the manufacturer's instructions. In addition to testing one control each eight hours, the combination of controls and calibrators used each day of testing must include a high and low value.
	All quality control activities must be documented.	
D4282	In addition, for blood gas analyses, the laboratory must-- (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;	
D4284	(b) Test one sample of control material each eight hours of testing;	

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D4285	(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and	If blood gas analysis is performed with an instrument that does not internally verify the calibration at least every thirty minutes, then a calibrator or control must be tested each time patient specimens are tested.
D4288	(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.	It is not the intent of this requirement to require the laboratory to mai ntain records of each auto-calibration. Controls should be rotated to check normal, alkalosis and acidosis levels. Laboratories performing high complexity, modified, or in-house moderately complex blood gas testing, or performing testing with products not cleared or approved by the FDA meet the calibration requirements of §493.1217 if the laboratory calibrates the instrument in accordance with manufacturer's specifications. If the method was put into use after 9/1/92, the laboratory must also meet the requirements of §493.1213, verifying that the activities under §493.1245 are acceptable. Control materials generally are not available to verify the reportable range at the very high range of patient results. When necessary, the laboratory may verify the results by splitting patient samples and assaying them on two different blood gas analyzers. For high complexity tests for which there are no calibration materials, such as T3 uptakes, the calibration verification requirements at §493.1217(b)(2)(ii) may be met by assaying PT specimens or control materials with known values or splitting patient samples for testing with another established method to verify the accuracy of the patient test results. In addition, if the laboratory performs this activity at least twice a year, it will be in compliance with §493.1709. For high complexity kinetic enzymes, the calibration verification requirements at §493.1217(b)(2)(ii) may be met by verifying the linearity of the procedure using a high enzyme level material such as a control, calibrator, or patient specimen and diluting it to cover the reportable range. "493.1245(a)-(d) Probes: How is the operator alerted when internal calibration verification results do not meet the laboratory's specifications? How frequently are calibrators and controls assayed by a mobile laboratory performing blood gas analysis?
D4289	**§493.1247 Condition: Endocrinology.** To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§493.1201 through 493.1221 of this subpart.	§493.1247 Guidelines: For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182.

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	All quality control activities must be documented.	§493.1249 Guidelines: For qualitative urine drug screens performed by thin layer chromatography, a negative control is not required. However, a control containing one or more drugs representative of each drug group reported, e.g. tricyclic antidepressants, barbiturates, that goes through each test phase (including the extraction process), is required. For gas chromatography and mass spectrometry used for drug confirmations, an analyte specific control is required for both qualitative and quantitative tests. (Use D4132 or D4135, as appropriate.) For comprehensive broad spectrum qualitative drug screening procedures using gas chromatography, a control material containing one or more drugs representative of each drug class reported, e.g., tricyclic antidepressants, barbiturates, (Use D4132) must go through each test phase, including the extraction process. (Use D4145.) For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182.
D4291	**§493.1249 Condition: Toxicology.** To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart.	
	All quality control activities must be documented.	
D4293	In addition, for drug abuse screening using thin layer chromatography-- (a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and	
D4294	(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.	
D4295	**§493.1251 Condition: Urinalysis** Except for those tests categorized as waived, to meet the quality control requirements for urinalysis, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221.	
D4296	**§493.1253 Condition: Hematology.** To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1253 Guidelines: For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. §493.1253 Probes: How does the laboratory prepare thick or thin smears for identifying malaria? (Use D4051.)
	All quality control activities must be documented.	

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D4298	(a) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation.	§493.1253(a) Guidelines: "Hours of operation" is defined as each shift of 8 consecutive hours the laboratory is in operation, including "on-call" shifts. When documenting standards/controls results, the laboratory should identify the shifts in which controls are tested with patients. For cell counting instruments of moderate complexity, cleared or approved by the FDA that have not been modified by the laboratory, the requirements of §493.1202(c)(3) are considered met if the laboratory follows the manufacturer's instructions for instrument operation (D4001) and two levels of controls are tested each eight hours of operation. For all tests excluding FDA-cleared or approved moderate complexity tests that have not been modified by the laboratory, calibration or calibration verification requirements of §493.1217 are considered met for cell counting instruments if two (2) levels of controls are tested each eight (8) hours of operation. The laboratory must perform calibration or calibration verification as specified by the manufacturer when any of the following occurs: o There is major preventive maintenance or replacement of critical parts, such as apertures, optical flow cells, circuit boards (use D4121); o Controls begin to reflect an unusual trend or are outside of acceptable limits (use D4122); o The manufacturer's recommendations specify more frequent calibration or calibration verification (use D4101 or D4113); or o The laboratory's established schedule requires more frequent calibration or calibration verification. (Use D4105 or D4123.) Whole blood high range calibration materials are not generally available to verify the upper limit of the reportable range for all cell counts. Therefore, laboratories may use patients with elevated cell counts that have been verified to establish this range as part of method verification. (Use D4074.) For instruments which perform hemoglobin, hematocrit, red and white blood cell counts, differentials, acceptable controls are 2 levels of assayed materials, or 1 level of assayed material and 1 patient specimen. Exception: For instruments that perform white blood cell differentials directly from blood films (smears), a commercial control or patient specimen (differential) that has been verified through repetitive testing or a manual differential cell count is an acceptable control and satisfies the requirements of §493.1202(c)(4) or §493.1218(b)(2), as appropriate. For non-manual hemoglobin procedures, two levels of controls are required each eight hours of operation. Acceptable controls are two levels of assayed material or hemoglobin standard; or one level of assayed material or hemoglobin standard and one patient specimen.

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		A patient specimen may be used to meet the requirement for a control, provided that the patient specimen was verified in the same run with the assayed material. The patient specimen must have a range of acceptable performance established for the difference between duplicates. The laboratory must establish criteria for an acceptable range of performance as required at D4173, D4129 or D4150, as applicable. §493.1253(b) Guidelines: For all manual cell counts, e.g., synovial fluids, CSF, semen, using a hemocytometer, the laboratory may meet the requirement for duplicate testing by counting two hemocytometer chambers from one dilution and satisfy the requirements of §493.1217(b) and §493.1218(b)(2). The control requirement is applicable only to manual white, red and platelet cell counts performed on whole blood and is not applicable to cell counts performed on other body fluids. For manual white, red (including reticulocytes) and platelet cell counts, one level of assayed material, or one procedural control, each eight hours of operation satisfies the requirements of §493.1202(c)(3) or (4), as applicable, or §493.1217(b) and §493.1218(b)(2), as applicable. "Procedural control" is defined as one of the following: o Duplicate dilutions of either an assayed control or a previously assayed patient specimen. These may be assayed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates. (This is the only acceptable procedural control for manual red blood cell counts.); or o White Blood Cell and Platelet counts may be compared with a value estimated from a blood smear. §493.1253(c) Guidelines: The laboratory performing non-manual coagulation tests subject to §493.1202(c) must either establish criteria or verify manufacturer's criteria for an acceptable range of performance as required in §493.1219(b). For all other non-manual coagulation procedures, the laboratory must establish criteria or verify manufacturer's criteria for an acceptable range of performance as required in §493.1218(d). §493.1253(d) Guidelines: The laboratory must either establish control limits or verify manufacturer's control limits for an acceptable range of performance as required in §493.1218(d).
D4300	(b) For non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of control each eight hours of operation.	
D4302	(c) For all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.	
D4305	(d) For manual coagulation tests- (1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and	
D4308	(2) Patient and control specimens must be tested in duplicate.	

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	§493.1255 Condition: Pathology. The laboratory must meet the applicable quality control requirements in §§493.1201 through 493.1221 and §§493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology.	
	All quality control activities must be documented.	
D4312	**§493.1257 Condition: Cytology.** To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.	§493.1257(a)(1) Guidelines: Cytology laboratories may receive reagents, solutions, and stains from a manufacturer in large volume stock containers. For ease in handling, portions of these reagents are usually decanted into smaller working containers, which must be labeled in accordance with §493.1205(d). Some manufacturers do not label stain or reagent containers with the expiration date, however lot numbers and package inserts refer to this information. (Use D4038 if the laboratory uses materials beyond the expiration dates or the materials have deteriorated.) The Papanicolaou staining procedure is a polychrome method which enhances differences in cellular morphology. The procedure utilizes a nuclear stain, hematoxylin and two cytoplasmic counterstains, OG-6 and EA. The Papanicolaou method is used for staining cytologic preparations because it provides well defined nuclear detail, stains cytoplasm of various cell types different colors, and renders transparent cytoplasm. There are a variety of formulas for making hematoxylin, OG-6, and EA stains. The actual staining technique may vary among laboratories depending on the type of stains used and the laboratories' modification of the staining method. Modifications of the staining procedure must include the four main steps of the standard Papanicolaou staining method: fixation, nuclear staining, cytoplasmic staining and clearing. The procedure manual and flow chart should contain staining times, rinsing times or number of dips. Laboratories may use staining procedures, other than the Papanicolaou method, for staining nongynecologic specimens.
D4313	(a) The laboratory must assure that (1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;	

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		§493.1257(a)(1) Probes: Review the written staining procedure for staining gynecologic specimens. Do the written procedures specify: a. Stains used (i.e., Harris, Gill or other type of hematoxylin, OG-6, modified OG-6, EA36, EA50, EA65, modified EA or the identity of a combination counterstain; b. Solutions used (water, alcohol, clearing reagent, acid and bluing reagent); c. Concentration of each solution used, i.e., percentage (%) of alcohol, acid, ammonium hydroxide or lithium carbonate solution; d. Length of time or number of dips slides are placed in each stain or solution; and e. Procedure for coverslipping slides? (Use D4051 for written staining procedures.) What time frames are specified in the procedure manual and flow charts for each step in the staining of cytology specimens using the Papanicolaou staining method? (Use D4051.) How does the laboratory ensure that the personnel staining slides follow the procedure defined in the procedure manual? (Use D4043.) What written procedures are used to prepare nongynecologic specimens? (Use D4051.) What criteria does the cytology laboratory use to determine the expiration date of stocks, reagents, working stains and solutions made in the laboratory? (Use D4038.) How does the laboratory ensure that the gynecologic and non-gynecologic stains have been tested to ensure predictable staining characteristics on a daily basis? What records does the laboratory have to document the staining quality of Pap smears?(Use D4154 for performance, and D4182 for records.)
D4314	(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;	§493.1257(a)(2) Guidelines: The laboratory must develop its own policies and procedures for the prevention of cross contamination between gynecologic and nongynecologic specimens. The majority of gynecologic specimens are glass slide preparations (Pap smears) that are fixed prior to transport to the laboratory. Nongynecologic specimens are generally not processed or fixed. In general, Pap smears are thicker than most nongynecologic preparations and require staining times which are different from those of nongynecologic specimens. Commonly used methods include separate staining dishes for various specimens, i.e., gynecologic specimens, CSF, sputa, other body fluids, separate staining times, i.e., gynecologic specimens in the morning and nongynecologic specimens in the afternoon, with the staining dishes washed in between, or a separatory funnel setup. §493.1257(a)(2) Probes: What does the laboratory do to ensure that cross contamination between gynecologic and nongynecologic specimens does not occur? (Use D4314.)

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D4315	(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and	§493.1257(a)(3) Guidelines: A monochromatic stain such as toluidine blue may be used to determine the cellularity of nongynecologic specimens. Once a specimen has been concentrated, usually by centrifugation, a small drop of specimen is placed on a slide. A drop of stain is placed next to the specimen, allowed to mix, and coverslipped. Cellularity is evaluated microscopically. Highly cellular specimens have a high potential for cross contamination and may be stained at the end of staining a group of patient specimens. §493.1257(a)(3) Probes: Is the cellularity of nongynecologic specimens checked prior to cytopreparation (staining)? If so, what procedure does the laboratory use to determine which fluids must be stained separately? (Use D4315.) What records does the laboratory maintain to document that stains are filtered or changed when necessary? (Use D4182.) §493.1257(a)(4) Guidelines: The report should clearly specify when the smear is unsatisfactory for evaluation and unsatisfactory slide preparations should not be reported as negative or normal. The following are examples of criteria which may be used by the laboratory to determine if a smear is unsatisfactory for diagnostic interpretation: obscuring inflammation, obscuring red blood cells, obscuring lubricant, excessive air-drying, excessive cellular degeneration, absence of endocervical components, smears containing too few epithelial cells. §493.1257(a)(4) Probes: What procedure has the laboratory developed for categorizing a slide preparation as unsatisfactory? Examples may include, but are not limited to, scant cellularity, obscuring blood, obscuring inflammation, or lack of endocervical component.) (Use D4049.) §493.1257(a)(5) Guidelines: The intent of this requirement is that cytology preparations are evaluated on the premises of a laboratory certified in cytology. §493.1257(b)(1) Guidelines: The maximum total number of slides an individual may screen is 100 per 24 hours regardless of site or laboratory. Although the regulation establishes this maximum number, not every individual will be able to accurately examine 100 slides in 24 hours. The laboratory must establish how many slides can be screened per day for each individual. Refer to §493.1257(c)(4) to insure that the technical supervisor has established a maximum number of slides that each individual is capable of evaluating. This 100 slide limit is also applicable to those technical supervisors who examine previously unevaluated cytology specimens and perform 10% rescreen.
D4316	the stains are filtered or changed following staining;	
D4317	(4) Diagnostic interpretations are not reported on unsatisfactory smears; and	
D4318	(5) All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.	
D4319	(b) The laboratory is responsible for ensuring that-- (1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (one patient per slide, gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual.	
D4320	Previously examined negative, reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissue pathology slides examined by a technical supervisor qualified under §§493.1449(b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§493.1449(b) and (k).);	

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D4321	(2) For purposes of workload calculations, each slide preparation (nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide.	§493.1257(b)(1) Probes: How does the laboratory ensure that each individual examining slides (cytotechnologists, general supervisors and technical supervisors in cytology, as applicable) examines no more that 100 slides in a 24-hour period regardless of site or location? §493.1257(b)(2) Guidelines: Slide preparations made using automated, semi-automated or other liquid-based slide preparatory techniques include specimens prepared by centrifugation, cytocentrifugation, filtering techniques, or monolayering techniques. Any electrical instrument used to assist in the adherence of cells to the slide is considered to meet this requirement. This requirement refers to slide preparatory techniques, not liquid based coverslips. Slides prepared by traditional methods (usually smears prepared by hand) are not included. Maximum Workload Limits Traditional Smear Technique 100 Slides Automated, Semi-Automated, Liquid-Based 200 Slides Combination of Techniques 100 - 200 Slides §493.1257(b)(2) Probes: How does the laboratory maintain records of individual workload limits when various types of slides are evaluated? (Use D4334.) §493.1257(b)(3) Probes: How does the laboratory monitor the number of slides examined by each individual and the number of hours spent examining slides? How does the laboratory ensure that persons employed at other sites or locations do not exceed the maximum of 100 slides in 24 hours? §493.1257(b)(3)(i) Probes: How are records maintained to verify that the maximum number of 100 slides are examined in no less than 8 hours, especially in the situation in which slides are screened at different sites or locations?
D4322	(3) Records are maintained of the total number of slides examined by each individual during each 24 hour period, irrespective of the site or laboratory, and the number of hours each individual spends examining slides in the 24 hour period;	
D4324	(i) The maximum number of 100 slides described in paragraph (b)(1) of this section is examined in no less than an 8 hour workday;	
D4325	(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula-- $\frac{\text{No. of hrs examining slides x 100}}{8}$ to determine maximum slide volume to be examined.	

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D4326	(c) The individual qualified under §§493.1449(b) or (k) who provides technical supervision of cytology must ensure that-- (1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology.	§493.1257(c)(1) Guideline: This requirement is in addition to the review and confirmation by a technical supervisor of all nongynecologic preparations as described under §493.1257(c)(2). §493.1257(c)(1) Probes: How does the laboratory ensure that every smear containing cells exhibiting reactive or reparative changes, atypical squamous/glandular cells, premalignant or malignant, condition is confirmed by the technical supervisor? How does the laboratory ensure that the technical supervisor is the only individual authorized to release his or her electronic signature for gynecologic reports requiring technical supervisor review?
D4327	The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology;	
D4328	(2) All nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor;	§493.1257(c)(2) Probes: How does the laboratory ensure that all nongynecologic cytological preparations are reviewed by the technical supervisor? For nongynecologic slide preparations, in the event of a computer generated signature, how does the laboratory ensure that the system is protected from use by unauthorized individuals?
D4330	(3) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases as defined in paragraph (c)(1) of this section; and	§493.1257(c)(3) Probes: What criteria are used for evaluating the slide examination performance of each individual? What records are maintained to document the technical supervisors evaluation of the slide performance of each individual? How does the technical supervisor ensure that feedback is provided on slide examination performance to each person evaluating slides? What mechanism is used to allow individuals an opportunity to discuss instances of misdiagnosis?

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D4333	(4) A maximum number of slides, not to exceed the maximum workload limit described in paragraph (b) of this section is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.	What feedback and training is provided to improve the performance of individuals responsible for incorrect results? (Use D4330 for feedback and D6120 for training.) §493.1257(c)(4)(i) Probes: How are records maintained to document the workload limit for each individual? (Use D4182.) What criteria does the technical supervisor use to determine the slide limit for each person who examines slides? §493.1257(c)(4)(ii) Probes: How does the technical supervisor determine when an adjustment is required? How are records maintained to document that workload records are reassessed at least every six months and adjusted when necessary? §493.1257(d) Probes: What criteria did the laboratory consider in establishing its program for detection of errors in the examination of cytologic preparations and reporting of results? How is the program monitored? (Use D7001.) §493.1257(d)(1) Guidelines: The 10% rescreen of negative cases is not required for a one-person laboratory consisting of a technical supervisor or a laboratory which only employs pathologists qualified as technical supervisors. However, these laboratories must establish and follow a program to detect errors. This program must include, but is not limited to, cytologic/histologic correlations and retrospective review of negative cases ((d)(2) and (d)(3) of this section.) §493.1257(d)(1) Probes: How does the laboratory ensure that the rescreening program includes slides examined by each individual not qualified as a technical supervisor? What type of records does the laboratory have to indicate initial evaluation and rescreening results? (Use D4343.) How did the laboratory determine the individual(s) authorized to conduct the ten percent rescreen of all gynecologic cases interpreted to be negative for premalignant and malignant conditions as well as reactive, reparative and atypical smears? Does the laboratory review all slides from a case selected for rescreen? (Use D4341.) What type of documentation does the laboratory maintain to demonstrate that ten percent of the negative cases are rescreened? (Use D4182.)
D4334	(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in paragraph (c)(3) of this section.	
D4336	(ii) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.	
	(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results.	
D4341	(1) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions as defined in paragraph (c)(1) of this section that are examined by each individual not qualified under §§493.1449(b) or (k).	
D4342	This review must be done by a technical supervisor in cytology, a cytology general supervisor qualified under §493.1469, or a cytotechnologist qualified under §493.1483 who has the experience specified in §493.1469(b)(2).	

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D4343	(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information; (ii) Records of initial examinations and rescreening results must be available; and (iii) The review must be completed before reporting patient results on those cases selected.	§493.1257(d)(1)(i) Probes: What procedure is used to determine which slides are rescreened? Does this procedure vary so individuals screening slides do not know which slides will be chosen for rescreen? How does the laboratory determine whether Pap smears are from individuals with a high probability of developing cervical cancer? What criteria has the laboratory established to ensure that negative gynecological cases selected for rescreening, include, when possible, cases from patients that are considered high risk for cervical cancer? §493.1257(d)(1)(ii) Probes: What criteria does the laboratory use to determine discrepancies between initial evaluations and rescreening results? (Use D7055.) How does the laboratory resolve discrepancies between initial evaluations and rescreening examination results? (Use D7065.) §493.1257(d)(1)(iii) Probes: How does the laboratory ensure that the review is conducted prior to reporting patient results? §493.1257(d)(2) Probes: What criteria does the laboratory use to evaluate clinical information with cytology reports? What procedures does the laboratory follow when the clinical information on the requisition is inconsistent with the cytology report, e.g., an atrophic smear, usually characteristic of a post menopausal woman, on a 21 year old female with a history of LMP (last menstrual period) of 2-weeks-ago? How does the laboratory ensure that premalignant and malignant gynecological cases are correlated with histopathology reports, if available? What criteria does the laboratory use to determine a discrepancy between premalignant or malignant gynecologic reports and the correlating histology report? What mechanism is in place to obtain histopathology reports when testing was performed by another laboratory? (Use D4182 if the laboratory fails to document that the histopathology results were not available.) How does the laboratory evaluate discrepancies? What procedures does the laboratory follow when a discrepancy is identified?
D4347	(2) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant (as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies.	

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D4350	(3) For each patient with a current high grade intraepithelial lesion or above (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.	§493.1257(d)(3) Probes: How does the laboratory track previous cases on an individual patient? What criteria does the laboratory use to determine discrepancies when reviewing normal or negative slides from the past five years? How does the laboratory document the review?
D4354	(4) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in a reclassification as malignant or premalignant, as defined in paragraph (c)(1) of this section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section.	§493.1257(d)(4) Probes: When the laboratory reviews previous cases, does documentation indicate when specimens are not available?
D4360	(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall	§493.1257(d)(5) Probes: How does the laboratory evaluate each individual's case reviews against the overall laboratory statistics? What corrective actions are taken to resolve discrepancies? (Use D4360.)

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	statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.	§493.1257(e)(2) Guidelines: In cytology, great variation exists among the systems and terms a laboratory may use to report patient results on cytology reports. The laboratory must specify the descriptive nomenclature used for reporting patient results. This nomenclature must define the criteria used to classify patient results in a particular category in a clear and concise manner to ensure that all employees report patient results in a uniform, consistent manner. (Use D4062 and D7029.) Use of the Papanicolaou numerical system without narrative description is not acceptable. (Use D4364.) When cytology evaluations are recorded on worksheets in "code" how does the laboratory ensure that the correct verbiage is used in reporting the results? (Use D4062.) §493.1257(f) Probes: How does the laboratory indicate that the report is a corrected report (to avoid confusion with the initial report)? §493.1257(g) Guidelines: Slides must be stored by the laboratory in which the slides were actually examined for diagnosis. For clarification, we are providing examples to illustrate three scenarios: 1. A laboratory has a satellite location (certified in cytology) to which it refers some slides for examination. The satellite laboratory provides diagnosis on the cytology specimens. The slides examined at the satellite laboratory must be maintained by the satellite laboratory. 2. A laboratory refers all cytology specimens to a reference laboratory for examination. The reference laboratory examines all slide preparations, reports results only on normal, negative and unsatisfactory cases and returns at the request of the referring laboratory those cases that have reactive, reparative, atypical, premalignant or malignant conditions and 10% of the normal or negative cases for quality control review. The referring laboratory must maintain the slides of the cases that it examines and for which it provides diagnosis, i.e., slides exhibiting reactive, reparative, atypical, premalignant, or malignant conditions, and the 10% normal or negative cases for QC purposes. 3. A laboratory refers all cases to a reference laboratory for examination. The referring laboratory requests that the reference laboratory evaluate each patient specimen, for initial screening and return the slides and preliminary reports to the referring laboratory for diagnostic interpretation and final reporting. The referring laboratory must maintain all slides. Laboratory reports must specify the name and address of each laboratory that performs any testing or examines any patient specimens for diagnosis, i.e., preliminary and/or final reports. (Use D3056. Use D4182 for record storage and D4366 for slide storage requirements.) §493.1257(g) Probe: What documentation does the laboratory maintain to acknowledge the donation of each slide submitted to a proficiency testing program or loaned for other purposes? What protocol has been established to ensure prompt return of slides, when necessary?
D4363	(e) The laboratory report must- (1) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and	
D4364	(2) Contain narrative descriptive nomenclature for all results.	
D4365	(f) Corrected reports issued by the laboratory must indicate the basis for correction.	
D4366	(g) The laboratory must retain all slide preparations for five years from the date of examination,	
D4367	or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides.	
D4369	Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained.	
D4370	All slides must be retrievable upon request.	

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D4371	**§493.1259 Condition: Histopathology.** To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and paragraphs (a) through (e) of this section.	§493.1259 Guidelines: Tissue flotation baths in histology do not require temperature monitoring. However, paraffin containers on automatic processors and/or hot paraffin cabinets must be monitored closely for conformance with the defined temperature range for the paraffin in use. (Use D4025.)
	All quality control activities must be documented.	
D4373	(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains. Reaction(s) of the control slide with each special stain must be documented.	
D4375	(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.	
D4377	(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §493.1449(b) or §493.1449(l)(1) of this part.	
D4379	In addition, an individual who meets the requirements of §493.1449(b), §493.1449(l)(1) or §493.1449(l)(2), may examine and provide reports for specimens for skin pathology;	
D4380	an individual meeting the requirements of §493.1449(b) or §493.1449(l)(3) may examine and provide reports for ophthalmic pathology;	

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D4381	an individual meeting the requirements of §493.1449(b) or §493.1449(m) may examine and provide reports for oral pathology specimens.	§493.1259(d) Guidelines: For a computer generated report, the laboratory must ensure that only the qualified individual is authorized to use the electronic signature.
D4382	(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of the section. If a computer report is generated with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.	
D4384	(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.	
D4385	**§493.1261 Condition: Oral pathology.** To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 and §493.1259 of this subpart.	
	All quality control activities must be documented.	
D4387	**493.1263 Condition: Radiobioassay.** To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§493.1201 through 493.1221 of this subpart.	§493.1263 Guidelines: Radiobioassay includes tests that involve the in-vivo administration of radioactive materials to a patient and the subsequent measurement of radioactivity in body fluids. For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. §493.1263 Probes: How does the laboratory ensure the appropriate dosage for the administration of radioactive materials to patients? (Use D4022 or D4023, as applicable.) When commercial controls are not available, how does the laboratory ensure the accuracy of the test procedures? (Use D4144.)
	All quality control activities must be documented.	

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D4389	**§493.1265 Condition: Histocompatibility** In addition to meeting the applicable requirements for general quality control in §§493.1201 through 493.1221, for quality control for general immunology in §493.1241 of this subpart and for immunohematology in §493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section.	§493.1265 Guidelines: Cite all QC recordkeeping deficiencies at D4182. §493.1265(a)(1) Guidelines: Crossmatches for renal transplantation are usually done with the most recent available serum of the patient obtained within one month of the transplant or following a sensitizing event such as a transfusion. If a previous serum sample was more reactive than the current sample, the crossmatch should also include the previous most reactive sample(s), i.e., the one which demonstrates the broadest degree of reactivity with the panel. If antibody screening results indicate that more than one antibody may have appeared and disappeared in the past, selected reactive sample(s) should be included in the crossmatch. There are various acceptable protocols for selection of crossmatch samples which may vary from transplant center to center or from patient to patient. The laboratory should have clearly defined protocols available for the selection of crossmatch samples. If minimal or no information is available on patient sensitization from antibody screening, every effort should be made to obtain a sample less than 24 hours old for the final crossmatch. §493.1265(a)(1)(ii) Guideline: The minimum technique for crossmatching should be at least the basic or NIH procedure. A technique that enhances sensitivity is preferred, e.g., increased incubation time, wash steps and additions of antiglobulin. §493.1265(a)(1)(ii) Probes: What techniques are used for crossmatching? Does the laboratory define what positive crossmatch results are contradictory to transplantation? Under what circumstances are autocrossmatches performed? Under what circumstances are reverse crossmatches performed? (Mother (D)/Child (R)?) (Use D4050.)
	All quality control activities must be documented.	
	(a) For renal allotransplantation the laboratory must meet the following requirements:	
D4393	(1) The laboratory must have available and follow criteria for (i) Selecting appropriate patient serum samples for crossmatching;	
D4394	(ii) The technique used in crossmatching;	
D4395	(iii) Preparation of donor lymphocytes for crossmatching; and	
D4396	(iv) Reporting crossmatch results;	§493.1265(a)(2) Guidelines: Check duplicate copies of records for HLA typing, workup of MLC results, WBC crossmatch results, transplant information and antibody screening. All information on tray sheets such as that listed on the HLA Typing Sera Specifications chart on page C-185 must match the information on local trays. §493.1265(a)(2)(ii) Guidelines: Determine whether the laboratory obtains specimens at initial typing for periodic screening and for pretransplantation crossmatch, following potential sensitizing events such as transfusion, transplant loss, or infection, and at appropriate intervals defined by the laboratory and transplant center protocols.
D4397	(2) The laboratory must-- (i) Have available results of final crossmatches before an organ or tissue is transplanted; and	
D4398	(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;	

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D4399	(3) The laboratory's storage and maintenance of both recipient sera and reagents must-- (i) Be at an acceptable temperature range for sera and components;	§493.1265(a)(3)(i) Guidelines: The specificity of typing sera obtained locally should be confirmed in at least one other HLA laboratory. Sera received from other laboratories must be tested to ensure that they reveal the same specificities in the receiving laboratory. Each serum or monoclonal antibody must be stored at a temperature appropriate to maintaining the stability of its specificity.
D4400	(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and	
D4402	(iii) Ensure that all specimens are properly identified and easily retrievable;	
D4404	(4) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;	
D4408	(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;	§493.1265(a)(6)(i) Guidelines: HLA type is the identification of the human histocompatibility complex antigens (Human Leukocyte Antigens, HLA) on the surface of nucleated cells. The test is usually performed using human peripheral blood lymphocytes as target cells presenting the HLA antigens. The target cells are then reacted with tissue typing reagents (antibodies that identify each HLA antigen) in the presence of complement. Cells with the corresponding HLA antigen are bound by antibody and in the presence of complement are lysed indicating the HLA antigen is present on the cell surface. §493.1265(a)(6)(i) Probes: Are recipients typed for HLA-A, B, and DR? What typing trays are used? §493.1265(a)(6)(ii) Guideline: All organ donors should be HLA typed by the recipient center's laboratory, and the donor center laboratory if an organ is shared, to determine the degree of compatibility between donor and recipient. §493.1265(a)(6)(iii) Guideline: Records should indicate that results from redefinition and retyping are updated and compared. §493.1265(a)(6)(iii) Probe: How are discrepancies noted and resolved as the result of redefinition and retyping?
D4414	(6) The laboratory must-- (i)HLA type all potential transplant recipients;	
D4415	(ii) Type cells from organ donors referred to the laboratory; and	
D4416	(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;	

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D4420	(7) The laboratory must have available and follow criteria for- (i) The preparation of lymphocytes for HLA-A, B and DR typing;	§493.1265(a)(7)(i) Probes: Do tests used to identify Class II antigens use purified B cells or a technique that discriminates between T and B cells? If no, explain. (One color fluorescence with monospecific DR sera is an acceptable procedure.) Are there separate procedures for each type of specimen used (peripheral blood, lymph nodes and spleen)? §493.1265(a)(7)(ii) Guidelines: For HLA serologic typing, each batch of complement must be tested to determine that it mediates cytotoxicity in the presence of a specific antibody, but is not cytotoxic in the absence of a specific antibody. If diluted complement is to be used, the test must employ multiple dilutions of complement to ensure that it is maximally active at least one dilution beyond that intended for use. If undiluted complement is used, calculation of percent effectiveness (P.E.) is an acceptable method. The test should be carried out with at least two antibodies which should react with at least two different cells, and at least one cell which should not react. A strong and a weak antibody should be selected for the test, or serial dilutions of a single serum may be used. (Use D4151.) For HLA assays, stains should be uniform in all wells. Confirm that the stain meets these criteria by microscopic examination of the trays. If there is debris, ascertain if the stain should be filtered or the pH adjusted. (Use D4154 or D4156, as appropriate.) The results of each batch of typing plates must be reviewed to determine which sera failed to react as expected and which sera had unexpected reactions. Future locally prepared typing plates and interpretation of commercially prepared typing trays should be revised, based on the results of those reviews. §493.1265(a)(7)(ii) Probes: What criteria was used to determine the acceptability of each batch of complement for HLA assays? How does the laboratory identify the typing trays used for each patient? (Use D4030.) §493.1265(a)(7)(iii) Probes: Does the laboratory have criteria: (1) For assignment of HLA antigens of recipient/donors; and (2) To identify antigens to which patients are immunized and allow for the assignment of antibody specificities? Do criteria for antigen assignment take into account basic principles of inheritance? For example: (1) No more than 2 (each) HLA-A, B, and DR antigens are assigned to any subject; or (2) When relatives are tested, are typing interpretations in accordance with the genetic relationships?
D4421	(ii) Selecting typing reagents, whether locally or commercially prepared;	
D4422	(iii) The assignment of HLA antigens; and	

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D4423	(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshops HLA-A, B and DR specificities for which reagents are readily available;	Do laboratory personnel follow the scoring system defined in the procedure manual? (Use D6175.) §493.1265(a)(7)(iv) Guidelines: Antisera for many "splits" and cross reacting specificities of major HLA antigens are unavailable to many laboratories. It is good laboratory practice for each HLA-A and HLA-B antigen to be defined by at least two sera, if all are operationally monospecific. If multispecific sera must be used, at least five partially non-overlapping sera should be used to define each HLA-antigen. If monoclonal antibodies are used, each antigen should be defined by at least two antibodies with private epitope specificity and two with public epitope specificity or at least 3 partially non-overlapping antibodies with public specificities. §493.1265(a)(7)(iv) Probes: How are the specificities of new typing sera (whether procured locally or obtained commercially) verified, e.g., by running new trays in parallel with known ones or against known cells? What records demonstrate that typing sera reactions are recorded regularly, reviewed, used to modify locally prepared typing trays and applied to all tray interpretations? (Use D3041 for records.) Are reagent trays adequate for typing of recipient and donor cells to define HLA-A, B, and DR specificities as required to determine splits and cross-reactivity, as listed on the HLA Typing Reagent Sera Specifications chart on page C-185?
	(8) The laboratory must-- (i) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected;	§493.1265(a)(8) Guidelines: A patient's antibody profile should be evaluated when the patient is entered on the transplant waiting list. In order to identify changes in the antibody profile, new samples should be received and screened at monthly intervals, or more often if there has been an immunizing event such as transfusion. The laboratory should have clearly defined criteria for potentially sensitizing events and protocols for appropriate screening. If any patients are to be screened at reduced intervals, the laboratory should document that such patients are not likely to have any significant change in antibody level or specificity in the absence of sensitization. It is irrelevant whether the patient is screened at the time of donor typing. This is when crossmatches are performed. Verify that positive and negative controls are included. Assaying a control serum of known specificity is recommended. §493.1265(a)(8)(i)(A) Probe: When does the laboratory verify that the antibodies in the serum from organ or tissue graft recipients have been characterized against histocompatibility antigens? (This is done using the screening cell panel.)
D4425	(A) At the time of the recipient's initial HLA typing; and (B) Thereafter, following sensitizing events and upon request; and	

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D4428	(ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits-- (A) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and	§493.1265(a)(8)(i)(B) Probe: How often does the laboratory obtain and test patient samples to ascertain if there has been a change in the patients antibody profile? §493.1265(a)(8)(ii) Guidelines: An antibody screen is performed to identify whether a patient's serum contains antibodies to one or more HLA antigens. This is accomplished by screening the serum against target cells from a suitable panel of 40-60 subjects who represent all of the major HLA-A, B specificities and common splits. A sufficient number of subjects must be used to ensure that they include all of the HLA antigens to which the most common HLA antibodies are directed. Cell panels of known HLA type must be available to prove the specificity of new antibodies. The panel cells should include at least one example of each HLA antigen the laboratory should be able to define and be from a variety of ethnic groups. A panel to search for antibodies useful in HLA typing should contain a sufficient number of subjects so that all available HLA antigens are represented as well as cells possessing only one defined HLA antigen at a locus ("blanks"). The cells should come from a variety of ethnic groups. Typing of the panel members should be updated as sera from certain specificities become available. To identify an antibody with certainty, additional cells containing and lacking the appropriate antigen as well as cross-reacting antigens should be tested. §493.1265(a)(8)(ii) Probes: Is the serum cell panel consistent from month to month? At what temperature are serum screen tests performed? (Use D4025.) §493.1265(a)(8)(ii)(B) Guidelines: Storage of at least some panel cells at -80°C or in liquid nitrogen may be necessary to insure availability of required antigens.
D4429	(B) If the laboratory uses frozen panels, it must have a suitable storage system;	

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D4430	(9) The laboratory must check-- (i) Each typing tray using-- (A) Positive control sera; (B) Negative control sera; and (C) Positive controls for specific cell types when applicable (i.e., T cells, B cells, and monocytes); and	§493.1265(a)(9) Guidelines: Positive and negative controls must be included with each serum tested on each frozen cell tray. Each typing tray must include at least one positive control serum, previously shown to react with all cells and one negative control serum which has been demonstrated to be non-cytotoxic. Typing results may be invalid if the positive control fails to react as expected. The negative control should either be one previously shown to lack antibody or should be from a healthy male with no history of blood transfusion. Cell viability in the negative control well at the end of the incubation must be sufficient to permit accurate interpretation of results. For most techniques, viability should exceed 80%. In assays in which cell viability is not required, results on positive and negative controls must be sufficiently discriminatory to permit accurate interpretation of results. §493.1265(a)(9) Probes: What controls for specific cell types, other than the routine controls, are used on each tray? What percentage of cell viability in the negative control is considered adequate for interpretation of results? For assays in which cell viability is not required, what is the criteria for interpreting the results of the positive and negative controls? At the start of mixed lymphocytes cultures (MLC), what percent of cell viability is required by the laboratory? §493.1265(a)(10) Guidelines: Some laboratories may not perform their own MLCs. If MLCs are performed in another facility, identify where the MLC test is performed and determine that the facility is appropriately certified. (Use D3073.) The MLC test is mandatory only for bone marrow transplantation. In some patients it is not possible to obtain sufficient cells or the cells have poor viability, making it impossible to obtain reliable HLA typing and/or MLC test. In these cases, the laboratory may be able to utilize DNA (RFLP or oligonucleotide) typing or some other methodology. Each histocompatibility testing laboratory must have a policy instructing when MLCs are to be performed. A number of laboratories no longer rely solely on the MLC but use the results in conjunction with the Cell Mediated Lympholysis (CML), Primed Lymphocyte Typing (PLT), or the Homozygous Typing Cell. In conducting the survey, recognize that the laboratories are increasingly using DNA probes in addition to the MLC and that this is an acceptable technique. The MLC method used may vary from micro, macro, 1-way, or
D4434	(ii) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level;	
D4436	(10) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4437	(11) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with §493.1269 of this subpart;	both 1-way and 2-way. The treatment of the stimulating cell population may vary also (radiation vs. mitomycin). Laboratories using 2 X 10^6 cells for stimulation and response employ Macro-MLC. The data are expressed in counts per minute of H Thymidine. The various methods used for calculating data include the stimulation index (SI) and relative response (RR). Controls used in the MLC test also vary: mitogen, 1 unrelated, more than 2 unrelated, fresh pool or frozen pool. Request that the laboratory provide its criteria for scoring and how it composes the narrative report on the donor's ability to transplant. Review the criteria for accepting or rejecting a run, and the acceptable patterns for the MLC test. The onsite inspection should confirm that the laboratory uses methods with adequate controls for the MLC test and runs all combinations, i.e., combinations of any given stimulator with any given responder. Each MLC test should include an autologous control and three or more unrelated cells for each responder cell tested. (Use D4434.) §493.1265(a)(10) Probes: How does the laboratory screen serum used in the culture medium for support of cellular proliferation, sterility and the absence of cytotoxic antibodies? (Use D4024.) §493.1265(a)(11) Guidelines: Determine if the ABO and Rh grouping is performed in a CLIA certified laboratory. If ABO and Rh are performed on site and reported, the laboratory must be successfully participating in a PT program in immunohematology. (See Subpart H.) The laboratory must also meet the quality control requirements for immunohematology at §493.1269. If tests are performed on referral, determine the name of the referral laboratory and its CLIA number. If the referral laboratory is not CLIA certified, use D3073. Histocompatibility laboratories that do not perform their own ABO grouping should have a copy of the referral report from a certified laboratory. §493.1265(a)(12) Guidelines: The specificity of each lot of antiserum used to agglutinate contaminating erythrocytes in leukocyte preparations should be verified with control red cells. §493.1265(a)(13) Guidelines: The evaluation of the competency of testing personnel includes split sample testing (including split cell exchange samples), use of different, previously typed samples, and rereading plates. Verification of a technical person's ability to reproduce results should not be based solely upon rereading plates. A form containing only the name of the technical person, the date, and a check mark is unacceptable, unless the specific activity for the month is noted. For example, "Reread plate TD103". Check result sheets with interpretations for the initials of the reviewer and the date of review. The result sheets should also contain the patient's name or identification number so that a cross check between the files and the result sheets can be made.
D4438	(12) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;	
D4439	(13) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4440	(14) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate inter-laboratory reproducibility.	§493.1265(a)(14) Guidelines: Cite a deficiency if the laboratory is not enrolled in a cell exchange program or is enrolled in a program, but fails to return the results. Among the available cell exchange programs are the Southeastern Organ Procurement Foundation (SEOPF) program (a national program which tests quarterly) and the Terasaki/UCLA program (a national program which exchanges cells monthly) and the American Society for Histocompatibility and Immunogenetics/College of American Pathologists (ASHI/CAP) program. Identify the name or describe the cell exchange program used. For laboratories participating in a local exchange, record information concerning the frequency of exchange, difficulty of cell identification (antigen occurrence), viability of the cell, and the grading system. Performance criteria in the exchange program should be evaluated according to the antigens defined by the laboratory which must include the antigens listed on the HLA Typing Reagent Sera Specifications chart on page C-185. A laboratory should not be expected to identify cells that are not included [listed] on the chart on page C-185. If a laboratory performs poorly in a cell exchange program, confirm that the laboratory identified the cause of the poor performance and resolved the problem showing documentation of the action taken, e.g., cell 2501, Terasaki Cell Exchange, insufficient sample with low viability--unable to test. Action: Notified Terasaki of problem, March 1, 1990. (Use D7033 and D7066.) §493.1265(b)(1) Guidelines: In cases where recipients are at high risk for allograft rejection, e.g., recipients with histories of allograft rejection, recipients with high levels of preformed Class I HLA antibodies, donors and recipients should be typed for HLA-A, B and DR antigens, whenever possible. (Use D4414 and D4415.) Recipients should be screened whenever possible, for the presence of anti-HLA-A or B lymphocytotoxic antibodies to identify those at high risk for allograft rejection or transfusion reaction. (Use D4425.) §493.1265(b)(2) Probes: Are MLC tests performed in both directions for bone marrow transplantation? §493.1265(b)(3) Guidelines: In those patients that have demonstrated presensitization, it is required to carry out the crossmatch prior to transplant. The period of time at which organs such as liver, pancreas and heart remain viable after removal from the donor is often not sufficient for the laboratory to complete the crossmatch. It is, therefore, standard practice to do a retrospective crossmatch if the patient has been shown to have no preformed antibodies by prior screening. Failure to do a crossmatch prior to transplant is not a deficiency, provided emergency transplant circumstances are documented.
	(b) If the laboratory performs histocompatibility testing for-- (1) Transfusions and other non- renal transplantation, excluding bone marrow transplantation, all the requirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures, must be met;	
	(2) Bone marrow transplantation, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and	
D4442	(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations.	
D4443	The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4444	(c) Laboratories performing HLA typing for disease-associated studies must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.	§493.1265(c) Guidelines: Cell controls must be tested on each batch of typing trays. The control cells should include at least two cells known to express the specified antigen. The control cells should also include two cells for each cross reacting antigen which might be confused with the specific antigen. The control cells should also include at least two cells lacking the specific and cross reacting antigen. (Use D4434.) Serum controls must be tested at the time of typing and must include a positive and a negative control. Serum controls should also include two sera for each antigen which crossreacts with the specified antigen, if available. (Use D4434.) §493.1265(c) Probes: When typing for a single antigen for disease associated studies, are the sera used to identify the specific antigen adequate (2 mono or 1 mono + 2 duospecific)? (Use D4434.) When tests for a single antigen are performed for disease associated studies: o Is each batch of trays tested with control cells? o Do the control cells include cells from at least two subjects possessing the specified antigen? o Do the control cells include cells from at least two subjects for each antigen crossreactive with the specified antigen? o Do the control cells include cells from at least two subjects lacking the specified antigen and its crossreacters? (Use D4434.) §493.1265(d) Guidelines: In many cases the Organ Procurement Organization is responsible for ensuring that the donor is tested for HIV reactivity, and the testing may be referred to a laboratory that is not performing the histocompatibility testing.
D4445	(d) For laboratories performing organ donor HIV testing the requirements of §493.1241 of this subpart for the transfusion of blood and blood products must be met.	

INTERPRETIVE GUIDELINES - LABORATORIES

COMMONLY AVAILABLE

HLA TYPING REAGENT SERA

A1	B45 (12)	Cw6
A2	B13	Cw8
A3	B14	DQw1
A9	B15	DQw2
A23 (9)	B62 (15)	DQw3
A24 (9)	B16	DR1
A10	B38 (16)	DR2
A25 (10)	B17	DR3
A26 (10)	B18	DR4
A11	B21	DR5
A19	B22	DR6
A30 (19)	B27	DR7
A31 (19)	B35	DR8
A32 (19)	B37	Drw52
A33 (19)	B40	Drw53
A28	B60 (40)	
A29	B41	
B5	B42	
B51 (5)	B53	
B7	B70	
B8	Bw4*	
B12	Bw6*	
B44 (12)	Cwl-4	

Laboratories must identify either the broad specialty or, where applicable, the split of any major antigens.

The common splits are the ones shown before the number in parentheses.

*Bw4 and Bw6 are used to define other B antigens

HLA Antigens For Which Typing Sera are **NOT** Readily Available

Sera Moderately Rare		Sera Extremely Rare	
Aw36		Aw66	(10)
Aw34	(10)	Aw74	(19)
B52	(5)	Aw69	(28)
B39	(16)	Aw43	
Bw57	(17)	Bw64	(14)
Aw68	(28)	Bw65	(14)
DRw11	(5)	Bw58	(17)
DRw12		Bw75-77	(15)
DRw13	(6)	Bw71	(70)
DRw9		Bw72	(70)
DRw10		Cw10	
Cw5		Cw11	
Cw7		DQ5-9	
		DRw14	(6)
		DRw15	(2)
		DRw16	(2)
		DRw17	(3)
		DRw18	(6)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4446	**§493.1267 Condition: Clinical cytogenetics.** To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §493.1201 through §493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1267 Guidelines: Review the extent of services provided in order to apply the applicable requirements in §§493.1201 through 493.1221. Determine which of the following services are provided: o Sex Chromatin: Barr Bodies, "X" or "Y" Bodies; o Tissue Cultures: skin, lung, placenta; o Bone Marrow Cultures; o Peripheral Lymphocyte Cultures; o Amniotic Fluid Cultures; o High resolution chromosome analysis; o Special techniques such as: - Fragile "X" studies; or - Sister chromatid exchange; o Karyotype analysis; - photographic and/or computerized methods; o Transplant studies; o Chromosome staining (banding techniques) such as: - Qinacrine fluorescence (Q Banding); - Giesma/trypsin (G Banding); - Sodium phosphate/acridine or giesma/heat (R Banding); or - Barium hydroxide/heat (C Banding); - Nuclear organizing Region - Silver Stain (NOR); - Distamycin A/4-6-diamidino-2-phenylindole (DA/DAPI); or - Giemsa 11 (pH 11.0 for heterochromatin)(G 11). §493.1267 Probes: Prior to routine use, how does the laboratory check culture media for the following: o pH (amniotic cell cultures should be kept between pH 6.8 and 7.8); (Use D4160.) o Sterility/contamination (Use D4159.); and o Ability to support growth? (One example of an acceptable method for testing the ability of the media to support growth is the comparison of the results, e.g. numbers of useable metaphases per culture) between parallel cultures planted with new and established media. (Use D4160.) How does the laboratory ensure that cultures are incubated for a sufficient length of time for active cell division to be initiated? (Use D4022 or D4023, as appropriate.)
	All quality control activities must be documented.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		he incubation times may vary for each diagnostic area, i.e., cancer cytogenetics, prenatal cytogenetics and detection of constitutional abnormalities. The following list contains approximate incubation times: o Amniotic fluid - in situ 5-15 days flask 5-21 days o Chorionic villus - direct 0-2 days culture 5-21 days o Peripheral blood - Unstimulated (Leukemia) 1-4 days, but may be as long as 7 days for some rare disorders Constitutional - Routine 2-4 days Fragile X 2-4 days High resolution 2-4 days o Bone marrow (cancer) 0-2 days (usually; however, selected disorders such as chronic lymphocytic leukemias may be as long as 5+ days) o Tissues (non-cancerous) 1-6 weeks o Tissues (cancerous) 0-10 days (usually; however, rarely as long as 4+ weeks) At what intervals are amniotic fluid and fibroblast cultures checked for growth, and when applicable, is the physician notified of the need for a repeat specimen? (Use D4050 and D4002.) (Amniotic fluid cultures should be fully characterized before the fifteenth (15th) day after planting and tissue cultures should be held for at least 2-3 weeks before reporting a final no growth report.) (Use D4022 or D4023, as appropriate.) How does the laboratory quality control: o Routine stains? (Use D4154.) (Each day one slide should be stained to check timing for critical steps in staining procedures. Adjustments are made as needed.) o Fluorescent stains? (Use D4156.) o Reagents? (Use D4151.) o Chromatin counts? (Use D4131 or D4144, as applicable.) (Some examples of control materials for X and Y chromatin counts are known specimens, spreads and smears.) How many incubators does the laboratory use exclusively for amniotic cultures? (Use D4024.) (For "closed system" culturing, at least one incubator should be used exclusively for amniotic cultures. For "open system" culturing, two incubators on separate electrical circuits are recommended to be used exclusively for amniotic cultures. (Use D4017.) What precautions has the laboratory instituted to maintain incubating cultures in the case of a power failure? (Use D4025.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4448	(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells.	What band level of resolution is used by the laboratory to rule out structural defects, i.e., routine or 400-500 band stage, or high resolution or 650-850 band stage? (Use D4455.) High resolution chromosome analysis should refer to studies done above the 550 band stage. (Above 650 band stage for an unfocused study. A focused study should be done at a level of resolution at which the band in question is clearly separated from surrounding bands in one member of the homologous pair in question.) (Use D4455.) For what type of cultures does the laboratory monitor chromosome analysis success rate? What percentage of amniotic cultures fail? (Failure rate should not exceed 2% for amniotic fluid, chorionic villus, blood; 5% for tissue culture; and 10% for bone marrow.) (Use D4170 and D7001, as applicable.) Is there written documentation of investigation of culture attempts that failed to yield metaphases? Has there been a cluster of culture failures within the last year? What caused these culture failures? (Use D4170, D7033, and D7066.) For what types of cultures does the cytogenetics laboratory routinely attempt to obtain follow-up information for analysis of correlation between clinical findings and cytogenetic findings: o Amniotic fluid cultures? o Leucocyte cultures? o Bone marrow cultures? o Fibroblast cultures? (Use D7050-D7052, D7054.) How many people analyze the karyotype? (At least two qualified people are recommended.) (Use D6117.) §493.1267(a) Guidelines: Some examples of "atypical results" are: o Sex "X" chromosome body is divided into two parts instead of one solid barr. (This should be verified by karotyping.); o Q band for "Y" chromosome is small and may be something else. (This should be verified.); o A decreased number of Barr body positive cells (<20%); o A decreased number of "Y" positive cells (<50%); and o Unusually small Barr bodies. §493.1267(a) Probes: If less than 100 cells are counted, when sex is determined by X and Y chromatin counts, how did the laboratory determine the minimum number of cells to be examined? What type of confirmatory testing is performed by the laboratory for atypical results?
D4449	Confirmatory testing such as full chromosome analysis must be performed for all atypical results.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(b) The laboratory must have records that reflect	§493.1267(b) Guidelines:
D4450	the media used and document the reactions observed,	
D4452	number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread,	
D4455	and the quality of the banding; that the resolution is sufficient to support the reported results;	
D4457	and that an adequate number of karyotypes are prepared for each patient.	

Culture Type		**Minimum No. of spreads counted per patient**	**Minimum No. of cells analyzed per patient**
Amniotic fluid			
	Flasks	15 cells from at least 2 independent primary cultures	5 cells
	in situ	15 cells from at least independent primary cultures	5 cells from different different primary cultures
	Many laboratories use a combination of the flask and in situ culture methods or use the flask method as a backup as to the in situ method.		
Chorionic villus			
	Direct	15 cells	5 cells
	Culture	as in amniotic fluid	
Peripheral blood			
	Constitutional	20 cells	5 cells
	Possible sex chromosome abnormality	30 cells (total)	5 cells
	For confirmation of chromosomally abnormal amniotic fluid results, or familial chromosome abnormality, examination of fewer cells is permitted.		
Blood (cancer)		20 cells	20 cells
Bone Marrow (cancer)		20 cells	20 cells
Tissue fibroblasts		15 cells from 2 independent cultures	5 cells split between

For fragile X analysis:
- o Males - at least 50-100 cells should be scored for negative analysis.
- o Females - at least 100-150 cells should be scored for negative analysis.

The presence of the Xq27.3 fragile site should be confirmed with chromosome banding. (Use D6117.)

Fragile X studies require low folate medium and media which includes treatment with antimetabolites such as fluorodeoxyuridine (FUdR), methotrexate, excess thymidine, fluordeoxycytidine (FdC), or other proven induction systems.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4458	(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.	Examine the karotypes and a slide from among the laboratory cases and determine if the quality of banding and resolution was sufficient to render the reported interpretation. Examination of the long arm on the 18th chromosome should demonstrate at least two clear black bands. (Use D4455.) §493.1267(b) Probes: For fragile X analysis, if a folate deficient medium is not used as described above, how does the laboratory assure the validity of the test system and the accuracy of results? (Use D4022 or D4023, as applicable.) How does the laboratory identify the fragile X chromosome? Do records document: o Observations made concurrently with the performance of each step in the examination of specimens/cultures. (Use D4450-D4457, as applicable); and o The number of cases reviewed, signed out and/or failed? (Use D6117.) How many photographic and/or computerized karotypes are prepared from each cell line? (A minimum of 2 is recommended.) (Use D4457.) How many spreads are counted for each chromosome analysis? (Chromosomes counts of 15-20 cells are recommended.) When mosaicism is suspected on the basis of a phenotype that does not fit with the karyotype, when sex chromosome abnormalities are suspected (these disorders are commonly mosaic), or when single trisomic cells are found during a study, an analysis of at least 50 cells is recommended. (Use D4448, D4452, D4457.) §493.1267(c) Guidelines: Review a sample of patient case files to determine if it is possible to go from the accession number to the patient's file with karyotypes, report and observation records, the microscope slide, photograph, or requisition forms. §493.1267(c) Probes: When photographs are taken, are the coordinates of the microscope noted for each cell counted? If not, how does the laboratory identify the cell for future reference? What system does the laboratory use to ensure that records reflect accurate patient identification when: o Photographing chromosome spreads (use D4458); or o Using computer systems to assist in karyotyping? (Use D4458.) Have laboratories that use a computer system for patient karyotyping verified the software used? (Use D4024.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4464	(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.	§493.1267(d) Guidelines: Appropriate nomenclature may include the International System of Cytogenetic Nomenclature (ISCN - 1985). §493.1267(d) Probes: Does the laboratory report include: o Type of banding used, if applicable; o Stage of cell mitosis when banded; o Number of cells counted and analyzed microscopically; o Number of cells from which photographic or computerized karyotypes were prepared; and o Estimate of the chromosomal band level of resolution achieved? Preliminary reports of karyotypes based on less than full analysis are acceptable if the diagnosis is clear. For what types of cultures are preliminary reports issued? These may include, but are not limited to, the following: o Bone marrow analysis (within 14 days); o Unstimulated blood cultures (within 14 days); and o Lymphocytes from newborns (within 7 days). What is the average length of time for reporting: (Use D3050) o Amniotic fluid cell cultures (90% of prenatal diagnosis cases should be signed out in 21 days); o Routine lymphocyte cultures (approximately 4-5 weeks); and o Fibroblast cultures (approximately 2-3 months)?
D4469	**§493.1269 Condition: Immunohematology** To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.	§493.1269 Guidelines For all devices, products, or test systems cleared or approved by the FDA as moderately complex that have not been modified by the laboratory, cite QC recordkeeping deficiencies at D6072. Cite all other QC recordkeeping deficiencies at D4182. For moderate complexity testing using FDA cleared or approved products that have not been modified by the laboratory, the requirements of §493.1202(c)(4) provide for the proper checking of antisera and reagent red cells using known positive and negative controls. For all other testing, e.g., compatibility testing, the requirements of §493.1218(b)(1) provide for the proper checking of antisera and reagent red cells using known positive and negative controls.
	All quality control activities must be documented.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Exceptions to §§493.1202(c)(4) and 493.1218(b)(1): The following chart defines the frequency and the type of quality control to be performed for each container of antisera and reagent red cells used for immunohematology testing: Reagent — Positive Control — Negative Control ABO Antisera — Each day of use — N/A Rh Antisera — Each day of use — Each day of use Other Anti-sera — Each day of use — Each day of use *Anti-human globulin sera — *Each day of use — *Each day of use ABO Reagent red cells — Each day of use — N/A Antibody Screening cells — Each day of use (at least one known antibody) — N/A In daily quality control testing it is sufficient to test antiglobulin serum for IgG only. Anticomplement activity can be checked, if desired, against complement coated RBC's but this need not be a routine procedure. *This requirement is satisfied by checking the antihuman immune globulin (Coombs Serum) in one of the following ways: o React anti-human globulin with a pre-sensitized reagent red blood cell which is either prepared commercially or by the laboratory; o Perform the quality control for antibody detection using a known antibody which is demonstrated by the addition of antihuman globulin; or o Add a pre-sensitized reagent red blood cell to all negative antiglobulin tests (direct antiglobulin, indirect antiglobulin, antibody detection and identification test) to indicate that antiglobulin serum present in the test was not inactivated by unbound globulins or diluted by excess residual saline, and that the negative results reflect true absence of reactivity in the test. Using green antiglobulin serum does not substitute for this control. For moderate and high complexity testing, the requirements of §§493.1202(c)(3) and 493.1217, respectively, are considered met if the laboratory meets the above control requirements.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4471	(a) The laboratory must perform ABO group	§493.1269 Probes: How does the laboratory ensure the reliability and potency of antisera and reagent red cells when multiple reagent racks are in use? (Use D4132 or D4006, as applicable.) §493.1269(a) Guidelines: A major crossmatch carried through the antiglobulin phase is not required if the recipient and donor typing and antibody screening procedures contain the following elements: o A method of collecting and identifying the blood samples of recipients and donors to ensure positive identification; o The determination of the ABO and Rh groups of the donor and recipient, using licensed blood grouping sera or their equivalent; o Antibody detection tests that will demonstrate significant alloantibodies active at 37°C in the serum or plasma of a previously transfused or previously pregnant donor; o The testing of the recipient's serum for unexpected alloantibodies, by the antiglobulin technique or an equally sensitive method that will demonstrate significant antibodies reactive with the donor's cells at 37°C; and o Procedures to expedite transfusions in life threatening emergencies and, if applicable, procedures for testing blood for neonatal transfusions and autologous transfusions. (The preceding guidelines are an excerpt from the 12/14/84 memorandum addressed from the FDA to all blood establishments.) There are numerous serological techniques suitable for detection of blood group antibodies. To select blood for a recipient, use the method(s) that: (1) Will detect as many clinically significant antibodies as possible; (2) Will not detect clinically insignificant antibodies; and (3) Will allow prompt delivery of blood to the recipient. Regardless of the procedures chosen, the antibody detection method must demonstrate clinically significant unexpected antibodies reactive at 37 degrees centigrade. In addition, the compatibility testing procedures must demonstrate ABO incompatibility. §493.1269(a) Probes: If unlicensed reagents are used, what criteria are employed by the laboratory to evaluate and determine the equivalent reactivity and suitability for the use of these unlicensed reagents? (Use D4024.) What is the laboratory's policy regarding compatibility testing for patients with a history of a prior antibody? What is the laboratory's policy regarding compatibility testing for patients with no history of a prior antibody? (Use D6175 or D4043, as applicable.) If the patient has been tested previously, how are results of current testing compared with interpretations of previous testing? (Use D7054.)
D4472	and D(Rho) typing,	
D4473	unexpected antibody detection,	
D4474	antibody identification	
D4475	and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR Part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR 640 et seq.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D4476	(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents.	What is the laboratory's policy for retyping, rescreening, and/or recrossmatching units which are not transfused at the originally requested time? (Use D6175 or D4043, as applicable.) How does the laboratory handle positive antibody screening test results? (Use D4022.) When a major crossmatch is compatible, but the recipient sample demonstrates a positive antibody screen, is the antibody identified prior to the release of the unit? (Use D4022.) If not, does the laboratory obtain written authorization from the physician prior to the release of the unit? (Use D4475.) §493.1269(c) Guidelines: The use of Anti-CD, Anti-DE or Anti-CDE is not required. Donor blood and prenatal blood specimens which test D(Rho) negative should be confirmed by further testing, which should include tests for Du (weak D). However, Du testing on recipient blood specimens and on donor blood and blood products typed (which includes Du testing) and labeled as D(Rho) negative is not required. When the Du test is performed and the Du is positive, a control system should be employed. The control system may consist of an autologous control with the Du test or performance of a direct antiglobulin test. §493.1269(d) Guidelines: The D antisera most commonly in use are: o High protein unmodified IgG antibody; or o Chemically modified IgG antibody Both types of reagents must be checked with cell controls (autologous control) in order to avoid false positive interpretations. The control systems which must be used in the test system are as follows: o High protein unmodified serum: The manufacturer's diluent, if available, may be used, however, 22% or 30% albumin may also be used with the test cells in the autologous control; or o Chemically modified serum: Manufacturer's diluent, 6% albumin or normal saline may be used with the test cells in the autologous control. However, if a concurrent test system which will detect autoagglutination is used, the requirement for an autologous control is met. A concurrent test system is the performance and interpretation of the direct and reverse ABO group.
D4477	For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.	
D4478	(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.	
D4479	(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.	

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D4480	**§493.1271 Condition: Transfusion services and bloodbanking.** If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products	§493.1271 Guidelines: Use D4480 if quality control under the Condition: Transfusion services and bloodbanking is not met due to significant deficiencies cited under D4481 to D4512. "Facility" as defined in 21 CFR 606.3(h) means any area used for the collection, processing, compatibility testing, storage or distribution of blood and blood components. In emergency situations, if blood or blood products are released for transfusion prior to testing, are there procedures in place to ensure the appropriate followup of positive test results with the recipient's physician? The quality control guidelines for transfusion services and bloodbanking include the applicable regulations in §§493.1271 through 493.1285 of this subpart as well as the information in the U.S. Food and Drug Administration (FDA) guidelines - Blood Bank Inspection Checklist and Report Instruction Booklet FDA Form-2609. Ensure that all confirmed fatal transfusion reactions identified during a facility survey, or obtained on the basis of a complaint investigation, have been investigated, and that the FDA has been notified. If they have not, notify: Food and Drug Administration Center for Biologics Evaluation and Research 8800 Rockville Pike - HFB-120 Bethesda, MD 20892 (Telephone 301-295-8191) Send the RO reports of all the confirmed fatal transfusion reactions identified. These reports are used to ensure that the facilities have properly notified FDA of fatal transfusion reactions and that all necessary followups have been conducted by both HCFA and FDA.
D4484	and that blood and blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients.	
	The facility meets this condition by complying with the standards in §§493.1273 through 493.1285 of this subpart.	
	§493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.	
	In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§493.1201 through 493.1221 of this part.	
D4485	(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606,	§493.1273(a) Guidelines: 21 CFR Part 606.20(a)-Personnel is not applicable.

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	and the testing laboratory must meet the applicable requirements of part 493.	§493.1273(c) Guidelines; Technical specifications intended for bag manufacturers, label makers and printers are given in a publication entitled "Guideline for the Uniform Labeling of Blood and Blood Components." Unless a laboratory participates in making its own labels, the laboratory need only be concerned that the labels it obtains are in compliance with FDA specifications, and that it uses them properly. Nevertheless, anyone involved with labeling should be familiar with the Guideline. For copies of the Guideline or for any additional information, refer inquirers to: Food and Drug Administration Center for Biological Evaluation and Research HFB 140 8800 Rockville Pike Bethesda, Maryland 20892 Phone requests are accepted at 301-295-8228 Machine-readable labels are generally not susceptible to verification of their manufacture and printing quality via the certification process. However, to the extent the informational content and other characteristics of labels are visually discernible, ascertain whether all labels comply with the specifications in the Guideline. To verify that the labels are in compliance: o Ascertain that each type of label, as placed on blood containers, includes the information listed in item G2 of the Checklist, HCFA-Form 282, FDA-Form 2609; o Ascertain that current printed circulars of information are available; o If ABO group is distinguished by the color of the label, make sure standard colors are used, i.e., blue for group O, yellow for group A, pink for group B, and white for group AB; o Ascertain that special message labels are of appropriate color and bear the appropriate legend; o Ascertain that the labels retain their color and clarity. If you find any that have been soiled by fluids or chemicals, the label should not be obscured by wrinkling, scuffing or smearing, and the label should adhere tightly to the bag; and o If a bar code reader is available in the laboratory and if the labels are imprinted with bar codes, machine-read a sample of blood bags to confirm that the machine readings correspond to the eye-readable label information. If any irregularities are detected during this inspection, advise the laboratory that it must immediately obtain containers of the proper type and quality from a supplier which complies with the labeling guideline. Cite the applicable deficiencies and inform the RO.
D4488	(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.	
D4489	(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.	

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D4490	(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.	§493.1273(d) Probes: What procedure does the laboratory use to positively identify the blood or blood products that are crossmatched and available for the recipient? What is the laboratory's procedure for releasing blood and blood products for transfusion? Does it ensure positive identification of the intended recipient with the blood or blood products? Does the laboratory have a policy to receive and transport blood to the patient's location? Is it being followed? (Use D4043 and/or D6175, as applicable.) How does the facility positively identify the patient for whom the transfusion is intended?
	§493.1275 Standard; Blood and blood products storage facilities.	§493.1275 Guidelines: Actual readings of temperature controlled storage areas must be recorded during the time that blood or blood products for transfusion are stored or maintained. Acceptable temperature ranges must be established and posted. Temperatures continuously monitored by a recording thermograph are acceptable. The charts must be retained to document that temperatures are maintained within the limits established by the facility. When the laboratory performs alarm checks, they should compare the temperature at which the alarm sounds to the temperature on the recording chart. Be aware that there may be various unconventional blood storage areas or facilities, e.g., operating rooms, nursing stations, long-term care facilities, dialysis units, where blood or blood products may be stored. Each blood storage area should be reviewed by you. Determine whether these storage areas are under the jurisdiction of the laboratory. §493.1275 Probes: How does the facility ensure that the appropriate temperature is maintained for each blood storage area on a continuous basis? What type of freezer does the facility use to prevent freezing and thawing of materials required to be maintained at 0°C or below (i.e., frost-free versus non-defrosting)? Does the facility have an emergency power source for the temperature alarm system? If the facility does not have an emergency power source, how does the facility ensure that blood is maintained at the appropriate temperature? At what temperature does the alarm activate? If the laboratory is not staffed 24 hours a day, seven days a week, how does the facility ensure prompt response to an activated alarm (evenings, weekends, holidays)? How often does the facility verify that the alarm will activate at this temperature?
D4493	(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.	
D4495	(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and	
D4496	(2) Inspections of the alarm system must be documented.	
D4497	(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.	

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		What other materials, which may adversely affect the blood supply, are kept in the refrigerator that is used for blood storage? What criteria does the facility have for determining if blood or blood products are suitable for reissue? §493.1277 Guidelines: When a facility does not directly provide immunohematological, i.e., bloodbanking, services onsite, review the agreement with the outside laboratory, i.e.,blood bank. Confirm written approval by the director of the facility of the procedures for procurement, transfer and availability of blood and blood products. Determine which services are provided directly by the facility and which are provided through agreement. Review the agreements and determine if the outside laboratory is CLIA certified. (Use D3073.) §493.1279 Guidelines: Determine who is responsible for the supervision of the investigation of transfusion reactions and verify the qualifications of this individual in accordance with the requirements in 42 CFR Part 493, Subpart M, for technical supervision in immunohematology. §493.1283 Guidelines: There is no specific timeframe for retaining samples of transfused blood. However, it is common practice to keep these samples for a minimum of 7 days after each transfusion.
	§493.1277 Standard; Arrangement for services.	
D4499	In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.	
	§493.1279 Standard; Provision of testing.	
D4501	There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with §493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of §493.1449(b) or §493.1449(q).	
	§493.1283 Standard; Retention of samples of transfused blood.	
D4508	According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions.	

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D4509	The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.	§493.1285 Guidelines: Examine records of transfusion reaction investigations for completeness and accuracy. Verify that investigations of transfusion reactions are conducted in accordance with the facility's established protocols. Records of each investigation must include each step in the investigation. §493.1285 Probes: Are problems detected during the course of the transfusion reaction investigation documented, and are procedures instituted to prevent a recurrence? (Use D7062-D7065.) For transfusion-related fatalities, see §493.1271.
	§493.1285 Standard; Investigation of transfusion reactions.	
D4510	The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.	
D4512	The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.	

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	Subpart M--Personnel for Moderate and High Complexity Testing	
	§493.1401 General. This subpart consists of the personnel requirements that must be met by laboratories performing moderate or high complexity testing, or both.	
	Laboratories Performing Moderate Complexity Testing	
D6000	**§493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory director.** The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.	§493.1403 Guidelines: The Condition: laboratory director is not met when the laboratory director: o Position is not filled; o Is not qualified; or o Does not fulfill the laboratory director's responsibilities. An individual qualified as laboratory director may not qualify as a technical consultant in a particular specialty or subspecialty unless he or she has the required testing experience.
	§493.1405 Standard; Laboratory director qualifications.	
D6001	The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and	§493.1405 Guidelines: Section 353(i)(3) of the PHS Act states "No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section."
D6002	must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.	
D6003	(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and	§493.1405(a) Guidelines: The term "State" as used in this provision, includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of Northern Mariana Islands, the Virgin Islands, Guam and American Samoa.
	(b) The laboratory director must-- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and	§493.1405(b) Guidelines: Currently approved boards are those listed in the regulations published February 28, 1992.

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	(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	§493.1405(b)(1)(ii) Guidelines: "Board certified" means the individual has completed all the designated board's requirements, including the examination. If the director is named in a current edition of the "Director of Medical Specialists" (published for the American Board of Medical Specialties by Marquis Who's Who, Inc., 300 East Ohio Street, Chicago, Illinois 60611) as appropriately board certified, this may be accepted as evidence of certification without needing further documentation. You may make a notation of this in the laboratory's file. Qualifications that are equivalent for certification include board eligibility,(i.e., the individual meets all education, training or experience requirements to take the examination, but has not actually taken and successfully completed the examination.) An individual who wishes to qualify as a director must supply evidence of this eligibility status. The designated boards, upon request, send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status. §493.1405(b)(2)(ii) Guidelines: The type of experience required under this regulation is clinical in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. Patient or medically oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is unacceptable to meet the requirement for laboratory training or experience. The laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1407. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. §493.1405(b)(2)(ii)(B) Guidelines: The 20 continuing medical education credit hours (CMEs) may be obtained concurrently while acting as laboratory director until September 1, 1993. Thereafter, the 20 CMEs must be obtained prior to qualifying as a laboratory director. The CME courses must emcompass preanalytic, analytic, and postanalytic phases of testing, and be of such quality as to provide the physician with education equivalent to the experience described in §493.1405(b)(2)(ii)(A). Courses related to laboratory payment and CPT coding would not fulfill this requirement.
	(2)(i) Be a doctor of medicine doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and	
	(ii) Have had laboratory training or experience consisting of:	
	(A) At least one year directing or supervising non-waived laboratory testing; or	
	(B) Effective September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or	
	(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or	
	(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and	
	(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis,or the American Board of Medical Laboratory Immunology; or	

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	(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;	CME courses are to be accredited by, or meet the same criteria as the Accreditation Council for Continuing Medical Educaiton (ACCME), and should be designated as American Medical Association Physician's Recognition Aware (AMA PRA) Category 1 credits. Obtain a list of ACCME-accredited providers from ACCME at the following address: ACCME 51-B Sherwood Terrace P.O. Box 245 Lake Bluff, IL 60044 (708) 295-1490 §493.1405(b)(2)(ii)(C) Guidelines: The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assurance, proficiency testing, patient test management, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. §493.1405(b)(3) Guidelines: See p. C-24 for the definition of and guidance for accredited institution. §493.1405(b)(6) Guidelines: For tests of moderate complexity, individuals qualify as laboratory directors, if on February 28, 1992, they previously qualified, or could have qualified under the Federal regulations, published on March 14, 1990, as a laboratory director. After February 28, 1992, individuals must meet the requirements at §§493.1405(b)(1)-(5) to qualify as a laboratory director, unless the individual can demonstrate compliance with §493.1405(b)(6), (that is, on February 28, 1992, he or she could have qualified as a laboratory director under Federal regulations published on March 14, 1990).
	(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;	
	(ii) Have at least one year of laboratory training or experience, or both; and	
	(iii) In addition, have at least one year of supervisory laboratory experience;	
	(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;	
	(ii) Have at least 2 years of laboratory training or experience, or both; and	
	(iii) In addition, have at least 2 years of supervisory laboratory experience;	
	(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or	
	(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.	
	§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992. The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.	

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	(a)The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b)The laboratory director must: (1)Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those requred for such certification; (2)Be a physician who: (i)Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (ii)Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (iii)Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (iv)Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (3)For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or	The requirements for a laboratory director under 42 CFR 493.1415, published March 14, 1990 (55 FR 9538) are as follows: (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (2) Be a physician who: (i)is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (ii)is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or (iii)is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification, or (iv)subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for certification; (4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i)is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties, or (ii)subsequent to graduation has had 4 or more years of full time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and in addition, either: (i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

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	possesses qualifications that are equivalent to those required for certification; (4)Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i)Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (ii)Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (5)With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (i)Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (ii)Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (iii)Held a bachelor's degree from an accredited institiution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-	

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	time laboratory experience; or (iv)Acheived a satisfactory grade through an acceditation conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (6)Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months laboratory direction requirement in paragraph (b)(5) of the section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1968 required by State law for a laboratory director license. As exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.	**NOTE:** The January 1, 1988, date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1968, required by State law for a laboratory director license. An exception to the July 1, 1971, qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975, and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.
	§493.1407 Standard; Laboratory director responsibilities.	§493.1407 Guidelines: If the laboratory has more than one person qualifying as director, the laboratory is required to designate one individual who has ultimate responsibility for overall operation and administration of the laboratory. The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory. In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., patient test management, proficiency testing, quality control, quality assurance.
D6004	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing	

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	personnel, or delegate these responsibilities to personnel meeting the qualifications of §§493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.	§493.1407(a) Guidelines: If the laboratory director is not qualified as a technical consultant or clinical consultant, he or she must employ individuals meeting the appropriate qualifications. §493.1407(c) Guidelines: If the director cannot practically provide personal, onsite supervision it must be demonstrated that the director: o Provides direction and consultation by telephone, as necessary; or o Delegates to qualified personnel specific responsibilities as provided in the regulations. The laboratory director may reapportion to a technical consultant, in writing, the responsibilities in: §§493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13). The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1407(e)(8) and (9).
D6005	(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.	
D6006	(d) Each individual may direct no more than five laboratories.	
D6007	(e) The laboratory director must- (1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;	§493.1407(d) Guidelines: An individual may serve as a director of 5 certified laboratories. An individual may serve as a technical consultant or clinical consultant for any number of laboratories.
D6010	(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and	§493.1407(e)(2) Guidelines: OSHA/EPA issues cannot be cited using these requirements. If an environmental problem that poses a severe risk is observed, the appropriate agency should be notified. If immediate jeopardy exists, the director should be informed immediately.
D6011	provide a safe environment in which employees are protected from physical, chemical, and biological hazards;	
D6012	(3) Ensure that-- (i) The test methodologies selected have the capability of providing the quality of results required for patient care;	

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D6013	(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and	
D6014	(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;	
D6015	(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--	
D6016	(i) The proficiency testing samples are tested as required under Subpart H of this part;	
D6017	(ii) The results are returned within the timeframes established by the proficiency testing program;	
D6018	(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and	
D6019	(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;	
D6020	(5) Ensure that the quality control and	
D6021	quality assurance programs are established and maintained to assure the quality of laboratory services provided and	
D6022	to identify failures in quality as they occur;	§493.1407(e)(6) Guidelines: If the laboratory fails to establish or verify acceptable limits for control samples, cite D4171 for FDA cleared or approved, moderate complexity testing. For in-house, modified manufacturer's procedures, or high complexity testing, cite D4147-D4149, as applicable. Also, consider if a deficiency exists at D6023. If this responsibility was delegated to the technical consultant, consider if a deficiency exists at D6042.
D6023	(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;	

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D6024	(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and	
D6025	that patient test results are reported only when the system is functioning properly;	
D6026	(8) Ensure that reports of test results include pertinent information required for interpretation;	
D6027	(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;	
D6028	(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;	
D6029	(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;	§493.1407(e)(14) Guidelines: The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.
D6030	(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent	

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	and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;	
D6031	(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and	
D6032	(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.	
D6033	**§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.** The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.	§493.1409 Guidelines: The Condition of technical consultant is not met when the technical consultant: o Position is not filled; o Is not qualified; or o Does not fulfill the technical consultant's responsibilities.
	§493.1411 Standard; Technical consultant qualifications.	§493.1411 Guidelines: The type of experience required under this regulation is clinical in nature. This means, examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is unacceptable to meet the requirement for laboratory training or experience.
D6034	The laboratory employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory.	

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	performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.	The term "laboratory training or experience" means that the individual qualifying has the training and experience in the specialties and subspecialties in which the individual is providing technical consultation. Technical consultants should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. §493.1411(b)(1)(ii) Guidelines: Qualifications that are equivalent for certification include board eligibility, i.e., the individual meets all education, training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a technical consultant must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and
D6035	(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.	
	(b) The technical consultant must-(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is	
	(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	
	(2)(i) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and	
	(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board on Internal Medicine are qualified to serve as the technical consultant in hematology); or	

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	(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and	§493.1411(b)(3)(4) Guidelines: See p. C-24 for the definition of and guidance for accredited institution. Some examples of how the one-year requirement for training or experience can be met are: o Medical technology internship; o 1 year experience performing non-waived tests in a particular specialty(ies) or subspecialty(ies); or o Performance of non-waived testing in a particular specialty(ies) or subspecialty(ies) on a part-time basis, eqivalent to 2080 hours. NOTE: §493.1411(b)(4) requires 2 years of laboratory training or experience and can be met by any combination equivalent to 2 years of laboratory training or experience.
	(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or	
	(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and	
	(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.	
	Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual, who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.	

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	§493.1413 Standard; Technical consultant responsibilities.	§493.1413 Guidelines: In a specialty in which neither the director nor testing personnel can qualify to provide technical consultation, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. Under these circumstances, the qualified person is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical consultant must be available to provide consultation and should spend time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies). §493.1413(a) Guidelines: Since the testing personnel usually will not have experience and training in all specialties, technical consultation is essential in identifying training needs and assuring that each individual performing testing receives regular in-service training and education. There should be documentation, such as a log book or training/discussion reports, to indicate the services provided or activities performed by the technical consultant. These activities should correlate with the responsibilities delegated to the technical consultant by the laboratory director. The technical consultant is responsible for evaluating the capabilities of the technical personnel and advising the director on proper test performance in the specialty.
D6036	The technical consultant is responsible for the technical and scientific oversight of the laboratory.	
D6037	The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.	
D6038	(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and	
D6039	(b) The technical consultant is responsible for-- (1) Selection of test methodology appropriate for the clinical use of the test results;	
D6040	(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;	
D6041	(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;	
D6042	(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;	

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D6043	(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;	
D6044	(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;	
D6045	(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;	
D6046	(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--	§493.1413(b)(8) Probes: What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures? Evaluations of technical and clinical consultants' performance is located at §493.1713, Quality Assurance.
D6047	(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;	
D6048	(ii) Monitoring the recording and reporting of test results;	
D6049	(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;	
D6050	(iv) Direct observation of performance of instrument maintenance and function checks;	

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D6051	(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and	
D6052	(vi) Assessment of problem solving skills; and	
D6053	(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.	
D6054	Thereafter, evaluations must be performed at least annually	
D6055	unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.	
D6056	**§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.** The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.	§493.1415 Guidelines: The Condition of clinical consultant is not met when the clinical consultant: o Position is not filled; o Is not qualified; or o Does not fulfill the clinical consultant's responsibilities.
	§493.1417 Standard; Clinical consultant qualifications.	
D6057	The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must--	
	(a) Be qualified as a laboratory director under §493.1405(b)(1), (2), or (3)(i); or	

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	(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.	
	§493.1419 Standard; Clinical consultant responsibilities.	
D6058	The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.	
D6059	The clinical consultant must-- (a) Be available to provide clinical consultation to the laboratory's clients;	
D6060	(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;	§493.1419(c) Probes: Has the clinical consultant reviewed the reports to ensure that test results include patient information required for specific patient interpretations?
D6061	(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and	
D6062	(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.	
D6063	**§493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.** The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.	§493.1421 Guidelines: The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, and ensuring that these responsibilities are specified in writing by the director, and that the responsibilities are appropriate to ensure compliance with the requirements concerning reporting and recordkeeping, quality control monitoring, quality assurance activities and proficiency testing participation. Cite this deficiency only when compliance problems are found in these areas that can be directly related to insufficient numbers of testing personnel. (Use D6028, which relates the finding of insufficient personnel to director responsibilities.)

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	§493.1423 Standard; Testing Personnel qualifications.	§493.1423 Guidelines: The laboratory director is responsible for ensuring the testing personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of testing performed. The experience required is clinical in nature. This means, examination of and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. (Use D6029). Each individual must have documentation of training applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he/she has the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing. For example, if the individual performs a rapid Strep test, he/she should be able to demonstrate the skills for: o Proper specimen handling prior to testing, e.g., assuring the specimen is properly labelled and received and tested within appropriate timeframes, the swab is received at the proper temperature, and the ampule on the swab containing transport media is broken; o Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using reagents that are not outdated, are at the proper temperature, and of the same lot number, accurate timing of all steps in the procedure, proper performance of quality control procedures; and o Proper reporting of patient test results in accordance with the laboratory's policies, e.g., notifying the person authorized to receive test results of a positive result, not reporting the test result if quality control fails. Training may include, but is not limited to, attendance at: o Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital; o On-site or off-site instrument trainings given by a manufacturer, e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory; o Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, ASCT; o Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations; o A formal laboratory training program; or o Inservices offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel. Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialled by the attendees indicating attendance at a training session/inservice, certificates from organizations providing the training session, workshop, conference, specialty course.
D6064	Each individual performing moderate complexity testing must-- (a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and	
D6065	(b) Meet one of the following requirements: (1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (2) Have earned an associate degree in a chemical, physical or 4biological science or medical laboratory technology from an accredited institution; or	

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	(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (4)(i) Have earned a high school diploma or equivalent; and	§493.1423(b)(1) Guidelines: See p. C-24 for the definition of and guidance for accredited institution. §493.1423(b)(3) Guidelines: Equate similar military courses with different titles. Evaluate the course length and content to assure that it provides effective training for testing personnel. Refer to A Guide to the Evaluation of Educational Experience in the Armed Services, American Council on Education, Washington, D.C. §493.1423(b)(4) Guidelines: Personnel qualifying under this requirement must have a high school diploma or GED. §1493.1423(b)(4) Probes: How does the laboratory assure that personnel receiving orientation and training have the necessary skills for properly performing assigned responsibilities?
D6066	(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.	
D6067	Such training must ensure that the individual has-- (A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;	
	(B) The skills required for implementing all standard laboratory procedures;	
	(C) The skills required for performing each test method and for proper instrument use;	
	(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;	
	(E) A working knowledge of reagent stability and storage;	
	(F) The skills required to implement the quality control policies and procedures of the laboratory;	
	(G) An awareness of the factors that influence test results; and	

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	(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.	
	§493.1425 Standard; Testing personnel responsibilities.	
D6068	The testing personnel are responsible for specimen processing, test performance, and for reporting test results.	
D6069	(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.	
D6070	(b) Each individual performing moderate complexity testing must- (1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;	
D6071	(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;	
D6072	(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;	

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D6073	(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;	
D6074	(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and	§493.1425(b)(5) Guidelines: If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite D6029 under director responsibilities. Some examples of problems that may adversely affect patient test results may include, but are not limited to: o A pleural fluid that is mislabeled and, therefore, is processed as a urine culture; o Performing a potassium on a hemolyzed sample; or o Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.
D6075	(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance	
	Laboratories Performing High Complexity Testing	
D6076	**§493.1441 Condition: Laboratories performing high complexity testing; laboratory director.** The laboratory must have a director who meets the qualification requirements of §493.1443 of this subpart and provides overall management and direction in accordance with §493.1445 of this subpart.	§493.1441 Guidelines: The Condition of laboratory director is not met when the laboratory director: o Position is not filled; o Is not qualified; or o Does not fulfill the laboratory director responsibilities.
	§493.1443 Standard; Laboratory director qualifications.	§493.1443 Guidelines: Section 353(i)(3) of the PHS Act states "No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section." The term "State" as used in this provision, includes the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of Northern Mariana Islands, the Virgin Islands, Guam and American Samoa.
D6077	The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.	
D6078	(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and	

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	(b) The laboratory director must- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and	§493.1443(b)(1)(ii) Guidelines: Qualifications that are equivalent for certification include board eligibility, i.e., the individual meets all education,training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a director must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training, or experience as required by the board to be eligible to take the examination and must have confirmation of eligibility status. §493.1443(b)(2)(i) Guidelines: The residency program should provide the director the knowledge in principles and theories of laboratory practice including: quality control and quality assurance, proficiency testing, patient test management, and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. §493.1443(b)(2)(ii) Guidelines: The type of experience required under this regulation is clinical in nature. This means directing or supervising personnel who examine and perform tests on human specimens for the purpose of providing information that is used in diagnosing, treating, and monitoring a patient's condition. This experience may include the laboratory director personally examining and performing tests on patient specimens. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is unacceptable to meet the requirement for laboratory training or experience. The laboratory director should have documentation, e.g., signed procedure manuals, test reports, worksheets and workcards, that indicates the director assumes the responsibilities in §493.1445. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. §493.1443(b)(3) Guidelines: See p. C-24 for the definition of and guidance for accredited institution. Currently approved boards are those listed in the regulations published February 28, 1992. To qualify as a laboratory director of high complexity testing after September 1, 1994, individuals possessing a Ph.D. or Dr.P.H. must be board certified by an approved board.
	(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	
	(2) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and	
	(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or	
	(ii) Have at least 2 years of experience directing or supervising high complexity testing; or	
	(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and--	
	(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by HHS; or	

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	(ii) Until September 1, 1994, must have at least-- (A) Two years of laboratory training or experience, or both;	§493.1443(b)(3)(i) Guidelines "Board certified" means the individual has completed all the designated board's requirements, including the examination. If the director is listed in a current edition of the "Director of Medical Specialists" (published for the American Board of Medical Specialties by Marquis Who's Who, Inc., 300 East Ohio Street, Chicago, IL 60611) as appropriately board certified, this may be accepted as evidence of certification without needing further documentation. The surveyor may want to make a notation of this in the laboratory's file. §493.1443(b)(4) Guidelines: An individual is qualified as a laboratory director if he or she was serving as a laboratory director on or before February 28, 1992, and previously qualified or could have qualified as a laboratory director under Federal regulations published March 14, 1990. After February 28, 1992, individuals must meet the requirements at §493.1443(b)(1)-(3) to qualify as a laboratory director for high complexity. In accordance with the regulations, the requirements listed below may be used only for individuals meeting these qualifications and functioning in the position as of February 28, 1992. The requirements for a laboratory director under 42 CFR 493.1415, published March 14, 1990 (55 FR 9538) are as follows: (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (2) Be a physician who: (i)is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (ii)is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or (iii)is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification, or (iv)subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for certification; (4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i)is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of
	(B) Two years of experience directing or supervising high complexity testing; and	
	(C) On September 1, 1994, individuals must meet the qualifications specified in paragraph (b)(3)(i) of this section;	
	(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or	

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		the laboratory specialties, or (ii)subsequent to graduation has had 4 or more years of full time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and in addition, either: (i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. **NOTE:** The January 1, 1988, date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1968, required by State law for a laboratory director license. An exception to the July 1, 1971, qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975, and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.
	(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (6)For the subspecialty of oral pathology, be certified by th American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or posses qualifications that are equivalent to those required for certification.	§493.1443(b)(5) Guidelines: Those individuals qualified after February 28, 1992, as directors solely under State law, will not meet this requirement.

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	§493.1445 Standard; Laboratory director responsibilities.	§493.1445 Guidelines: The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory. In determining whether the director responsibilities are met, consider deficiencies found in other conditions, e.g., patient test management, quality control, quality assurance, proficiency testing. If the laboratory has more than one person qualifying as a director, one individual must be designated as accepting ultimate responsibility for the overall operation and administration of the laboratory. §493.1445(a) Guidelines: An individual qualified as laboratory director under §493.1443 may not qualify as technical supervisor in a particular specialty or subspecialty unless he or she has the required training or experience. If the director of high complexity testing is not qualified to perform the duties of the technical supervisor or clinical consultant, he or she must employ individual(s) meeting the respective qualifications as noted in the February 28, 1992, regulations. §493.1445(d) Guidelines: An individual may serve as a director of 5 certified laboratories. However, an individual may serve as technical consultant, clinical consultant or technical supervisor for any number of laboratories. §493.1445(e) Guidelines: If the director cannot practically provide personal, on-site supervision, it must be demonstrated that the director: o Provides direction and consultation electronically or by telephone, as necessary; or o Delegates to qualified personnel specific responsibilities as provided in the regulations. The laboratory director may reapportion to a technical supervisor, in writing, the responsibilities in: §§493.1445(e)(3), (4), (5), (6), (7), (12), (13), and (14). The laboratory director may reapportion to a clinical consultant, in writing, the responsibilities in: §§493.1445(e)(8) and (9). The only responsibilities that may be delegated to the general supervisor are listed at §§493.1463(b)(1)-(4).
D6079	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.	
D6080	(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.	
D6081	(d) Each individual may direct no more than five laboratories.	
D6082	(e) The laboratory director must-- (1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;	

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D6083	(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and	§493.1445(e)(2) Guidelines: OSHA/EPA issues cannot be cited using these requirements. If an environmental problem that poses a severe risk is observed, notify the appropriate agency. If immediate jeopardy exists, inform the director immediately.
D6084	provide a safe environment in which employees are protected from physical, chemical, and biological hazards;	
D6085	(3) Ensure that-- (i) The test methodologies selected have the capability of providing the quality of results required for patient care;	
D6086	(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and	
D6087	(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;	
D6088	(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--	
D6089	(i) The proficiency testing samples are tested as required under subpart H of this part;	
D6090	(ii) The results are returned within the timeframes established by the proficiency testing program;	
D6091	(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and	
D6092	(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;	
D6093	(5) Ensure that the quality control and	

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D6094	quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;	
D6095	(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;	
D6096	(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and	
D6097	that patient test results are reported only when the system is functioning properly;	
D6098	(8) Ensure that reports of test results include pertinent information required for interpretation;	
D6099	(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;	
D6100	(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under §493.1489(b)(4);	
D6101	(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;	

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D6102	(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;	
D6103	(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;	
D6106	(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and	
D6107	(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.	§493.1445(e)(15) Guidelines: The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

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D6108	**§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.** The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.	§493.1447 Guidelines: The Condition of technical supervisor is not met when the technical supervisor: o Position is not filled; o Is not qualified; or o Does not fulfill the technical supervisor responsibilities.
	§493.1449 Standard; Technical supervisor qualifications.	
D6109	The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.	§493.1449 Guidelines: The type of experience required under this regulation is clinical in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Patient or medically-oriented experience, which is defined as the ordering of tests and interpreting and applying the results of these tests in diagnosing and treating a patient's illness is unacceptable to meet the requirement for laboratory training or experience. The term "laboratory training or experience" means that the individual qualifying has the training in and the experience with the specialties and subspecialties in which the individual is performing technical supervision. For technical supervisor, the requirement for training or experience can be met through any combination of training and/or experience in high complexity testing. This can be acquired subsequent to, concurrent with, or prior to obtaining academic requirements. Be flexible in evaluating laboratory training and experience. The specified training or experience may be acquired simultaneously in more than one specialty/subspecialty. Although it is unreasonable in §§493.1449(c)(5) and (j)(5) to expect four full-time years devoted only to high complexity microbiology testing and then four full-time years performing high complexity tests only in hematology, etc., to qualify under each specialty/subspecialty, it is necessary for the individual to have had continuous responsibilities in the specialty for the designated number of years and it would be more than simply performing an occasional test. Technical supervisors should have documentation of hands-on testing experience. This documentation may consist of, but is not limited to, the individual's initials on worksheets or work cards, attestation of the laboratory director to the experience the individual has, or formal laboratory rotation through a medical residency program or laboratory internship program. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens.
D6111	(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and	
	(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor -- (1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and	

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	(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.	A year of laboratory training or experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period. §493.1449(b)(2) Guidelines: Qualifications that are equivalent for certification includes board eligibility, i.e., the individual meets all education, training, or experience requirements to take the examination, but has not actually taken and successfully completed the examination. An individual who wishes to qualify as a technical supervisor must supply evidence of this eligibility status. The designated boards, upon request, will send a letter to the individual confirming his/her eligibility status. Note that some boards set time restrictions for taking the examination. For purposes of the regulations, the individual must meet the education, training or experience required by the board to be eligible to take the examination and must have confirmation of eligibility status.
	(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **bacteriology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and	§493.1449(c)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines. §493.1449(c)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.	
	(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **mycobacteriology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and	

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	(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6	§493.1449(d)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines. §493.1449(d)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	months experience in high complexity testing within the subspecialty of mycobacteriology; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.	
	(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **mycology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of	§493.1449(e)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines.

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	microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.	§493.1449(e)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **parasitology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or a doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or	§493.1449(f)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines. §493.1449(f)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.	
	(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **virology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	§493.1449(g)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines.

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	(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and	§493.1449(g)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.	
	(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of **diagnostic immunology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and	§493.1449(h)(1)(i) Guidelines: See §493.1449(b)(2) Guidelines. §493.1449(h)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(ii) Have at least 1 years of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology;or (4)(I) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology;or (5)(I) Have earned a bachelor's degree in a chemical, physical or biological science or medical technolgy from an accredited institution and (ii) Have at least 4 years of laboratory training or experience,or both,in high complexity testing for the specialty of dianostic immunolgy.	
	(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or	§493.1449 (i) (i) (ii) Guidelines: See § 493.1449(b)(2)Guidelines:

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	(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.	§493.1449(i)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.
	(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of **hematology**, the individual	

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	functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and	§493.1449 (j)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines. §493.1449(j)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.

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	(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.	
	(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **cytology**, the individual functioning as the technical supervisor must-- (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Meet one of the following requirements-- (A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (2) An individual qualified under §493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an	§493.1449(k)(1)(ii)(A) or (B) Guidelines: See §493.1449(b)(2) Guidelines.

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	individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under §493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.	
	(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **histopathology**, the individual functioning as the technical supervisor must-- (1) Meet one of the following requirements: (i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (2) For tests in dermatopathology, meet one of the following requirements:	§493.1449(l)(1)(i)(B) Guidelines: See §493.1449(b)(2) Guidelines.

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	(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (B) Meet one of the following requirements: (1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (3) For tests in ophthalmic pathology, meet one of the following requirements: (i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and--	§493.1449(l)(2)(i)(B)(1)(2) or (3) Guidelines: See §493.1449(b)(2) Guidelines.

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	(B) Must meet one of the following requirements: (1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in opthalmic pathology; or (ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or	§493.1449(l)(3)(i)(B)(1) or (2) Guidelines: See §493.1449(b)(2) Guidelines.
	(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of **oral pathology**, the individual functioning as the technical supervisor must meet one of the following requirements: (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or	

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	possess qualifications that are equivalent to those required for such certification; or (2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (3) An individual qualified under §493.1449(b) or paragraph (m)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.	
	(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of **radiobioassay**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and	§493.1449(n)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines.

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	(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (4)(i) Have earned a master's degree in a chemical,physical, biological or clinical laboratory science or medical technology from an accredited institution; and (ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.	§493.1449(n)(3)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.
	(o) If the laboratory performs tests in the specialty of **histocompatibility**, the individual functioning as the technical supervisor must either-- (1)(i) Be a doctor of medicine, osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and	

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	(ii) Have training or experience that meets one of the following requirements: (A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (ii) Have training or experience that meets one of the following requirements: (A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.	§493.1449(o)(2)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.
	(p) If the laboratory performs tests in the specialty of clinical **cytogenetics**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and	

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	(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.	§493.1449(p)(2)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions.
	(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of **immunohematology**, the individual functioning as the technical supervisor must-- (1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.	§493.1449(q)(1)(ii) Guidelines: See §493.1449(b)(2) Guidelines.
	Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty	

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	may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.	
	§493.1451 Standard: Technical supervisor responsibilities.	§493.1451 Guidelines: In a specialty in which neither the director nor the general supervisor can qualify to provide technical supervision, the laboratory may engage the services of a qualified person either on a part-time or full-time basis for this service. The technical supervisor is not required to be on the premises full-time or at all times tests are being performed in his/her specialty(ies). However, the technical supervisor must be available to provide consultation and is required to spend an amount of time in the laboratory sufficient to supervise the technical performance of the staff in his/her specialty(ies). There should be documentation, such as a log book or notes from training which indicate the technical supervisor performs his/her assigned duties. The technical supervisor is responsible for evaluating the capabilities of the testing personnel and the general supervisor's testing performance.
D6112	The technical supervisor is responsible for the technical and scientific oversight of the laboratory.	
	The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.	
D6113	(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and	
D6114	(b) The technical supervisor is responsible for-- (1) Selection of the test methodology that is appropriate for the clinical use of the test results;	

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D6115	(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;	
D6116	(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;	
D6117	(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;	
D6118	(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;	§493.1451(b)(7) Guidelines: In some instances, in-service training may be specifically related to an instrument or test, or may be very general in nature. The laboratory may establish its own format, content, and schedule or provide training on an as-needed basis. This is acceptable provided the laboratory does not have deficiencies related to test performance.
D6119	(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;	§493.1451(b)(8) Probes: What mechanism is used to ensure that testing personnel are following the laboratory's policies and procedures? When approved by the director, these policies and procedures may include manufacturer's instructions.
D6120	(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test	

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	procedures and report test results promptly, accurately and proficiently.	
D6121	The procedures for evaluation of the competency of the staff must include, but are not limited to-- (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;	
D6122	(ii) Monitoring the recording and reporting of test results;	
D6123	(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;	
D6124	(iv) Direct observation of performance of instrument maintenance and function checks;	
D6125	(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and	
D6126	(vi) Assessment of problem solving skills; and	
D6127	(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.	
D6128	Thereafter, evaluations must be performed at least annually	
D6129	unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.	

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	(c) In cytology, the technical supervisor or the individual qualified under §493.1449(k)(2)- (1) May perform the duties of the cytology general supervisor and the cytotechnologist , as specified in §§493.1471 and 493.1485, respectively;	
D6130	(2) Must establish the workload limit for each individual examining slides; (3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;	
D6131	(4) Must perform the functions specified in §493.1257(c);	
D6132	(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and	
D6133	(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.	
D6134	**§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.** The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.	§493.1453 Guidelines: The Condition of clinical consultant is not met when the clinical consultant: o Position is not filled; o Is not qualified; or o Does not fulfill the clinical consultant responsibilities.

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	§493.1455 Standard; Clinical consultant qualifications.	
D6135	The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care.	
	The clinical consultant must-- (a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); (b) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.	
	§493.1457 Standard; Clinical consultant responsibilities.	
D6136	The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.	
D6137	The clinical consultant must -- (a) Be available to provide consultation to the laboratory's clients;	
D6138	(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;	
D6139	(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and	
D6140	(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.	

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D6141	**§493.1459 Condition: Laboratories performing high complexity testing; general supervisor.** The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.	§493.1459 Guidelines: The Condition of general supervisor is not met when the general supervisor: o Position is not filled; o Is not qualified; or o Does not fulfill the general supervisor responsibilities.
	§493.1461 Standard: General supervisor qualifications.	§493.1461 Guidelines: The type of experience required under this regulation is clinical in nature. This means examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is considered acceptable experience. Research experience is also acceptable experience if it is obtained while performing tests on human specimens. A year of laboratory training and experience is equivalent to 2080 hours and could extend over more than one 12 calendar-month period. If all testing personnel have associate degrees, but none meet the training or experience requirement for general supervisor, the duties of the general supervisor must be fulfilled by an appropriately qualified individual. This individual need not be on-site at all times.
D6142	The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.	
D6143	(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified	
	as a-- (1) Laboratory director under §493.1443; or (2) Technical supervisor under §493.1449.	
	(c) If the requirements of paragraphs (b)(1) or (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or	

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	podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (ii) Have at least one year of laboratory training or experience, or both, in high complexity testing; or (2)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution; and (ii) Have at least two years of laboratory training or experience, or both, in high complexity testing; or (3) Have previously qualified or could have qualified as a general supervisor under 42 CFR 493.1427 of the Federal regulations published March 14, 1990, (55 FR 9538) on or before February 28, 1992.	§493.1461(c)(1)(i) Guidelines: See p. C-24 for the definition of and guidance for accredited institutions. §493.1461(c)(3) Guidelines: The requirements for a general supervisor under 42 CFR 493.1427, published March 14, 1990 (55 FR 9538) are as follows: (a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and (b) The laboratory supervisor- (1) Who qualifies as a laboratory director under §493.1415(b)(1),(2),(4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor. (2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii)Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory. (3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and (ii) Subsequent to graduation has had at least four years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory. (4)(i) Is qualified as a laboratory technologist under §493.1433(b)(1),(2),(3),(4) or (6) of this subpart; and

(d) For blood gas analysis, the individual providing general supervision must --
(1) Be qualified under §493.1461(b)(1) or (2), or §493.1461(c); or
(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and
(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or
(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and
(ii) Have at least two years of training or experience, or both in blood gas analysis.

(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory.
(5) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because he or she-
(i) Is qualified as a cytotechnologist under §493.1437; and
(ii) Has had 4 years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding 10 years;
(6) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

§493.1461(d)(3)(i) Guidelines:
NOTE: Many blood gas systems have been classified as moderate complexity tests; therefore, only moderate complexity personnel requirements are applicable. Use the test categorization list published in the Federal Register to confirm the complexity level of testing observed.

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	(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (1) In histopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l)(1); (2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(l) or(2); (3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(1)(3); and (4) In oral pathology, by an individual who is qualified as a technical supervisor under §§493.1449(b) or 493.1449(m).	§493.1461(e) Guidelines: In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately reponsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct onsite supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence of the technical supervisor by individuals qualified under §493.1489 must be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (l) or (m), as appropriate.
	§493.1463 Standard: General supervisor responsibilities.	§493.1463 Guidelines: Interview several testing personnel to elicit information about the duties they perform and the degree of supervision they receive.
D6144	The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.	
D6145	(a) The general supervisor-- (1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with	

	policies and procedures established either by the laboratory director or technical supervisor;	

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D6146	(2) Is responsible for providing day-to-day supervision of high complexity test performance by testing personnel qualified under §493.1489;	
D6147	(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(4); and	
D6148	(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.	
D6149	(b) The director or technical supervisor may delegate to the general supervisor the responsibility for-- (1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;	
D6150	(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;	

D6151 (3) Providing orientation to all testing personnel; and
(4) Annually evaluating and documenting the performance of all testing personnel.

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D6152	(c) Exceptions. For individuals qualified under §493.1489(b)(4), who were performing high complexity testing on or before January 19, 1993 the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.	
D6153	**§493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.** For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of §493.1469 of this subpart, and provides supervision in accordance with §493.1471 of this subpart.	§493.1467 Guidelines: The Condition of cytology general supervisor is not met when the cytology general supervisor: o Position is not filled; o Is not qualified; or o Does not fulfill the cytology general supervisor responsibilities.
D6154	**§493.1469 Standard: Cytology general supervisor qualifications.**	
D6155	The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must--	

(a) Be qualified as a technical supervisor under §493.1449(b) or (k); or

(b)(1) Be qualified as a cytotechnologist under §493.1483; and

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	(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.	§493.1469(b)(2) Guidelines: In addition to screening slides in a laboratory, the 3 years of full-time experience as a cytotechnologist can be fulfilled if the individual has been: o Teaching in schools of cytotechnology; o Teaching cytotechnology for residency programs in academic institutions; or o Participating in research directly related to cytotechnology, which includes screening slides, library research, and documentation.
	§493.1471 Standard: Cytology general supervisor responsibilities.	
D6156	The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under §493.1469.	
D6157	(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.	
D6158	(b) The cytology general supervisor must-- (1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;	

D6159 (2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under §493.1257(d));

D6160 (3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

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D6161	(4) Document the number of hours spent examining slides in each 24-hour period.	
D6162	**§493.14.81 Condition: Laboratories performing high complexity testing; cytotechnologist.** For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in §493.1483 to perform the functions specified in §493.1485. **§493.1483 Standard: Cytotechnologist qualifications.**	
D6163	Each person examining cytology slide presentations must meet the qualifications of §493.1449(b) or (k), or--	
D6164	(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, is such licensing is required; and (b) Meet one of the following requirements: (1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation; or (2) Be certified in cytotechnology by a certifying agency approved by HHS; or (3) Before September 1, 1992-- (i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8	§493.1483(b)(3)(i)(A) Guidelines:

hours of which are in biology; and
(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or
(B) Have received 6 months of

"A school of cytotechnology accredited by an accrediting agency approved by HHS" means a school or program approved by one of the accrediting agencies described in Subpart A of the Guidelines. (p. C-24.)

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	formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or (ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or (4) Before September 1, 1992, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under §493.1449(b) or (k)(1), and before January 1, 1969, must have-- (i) Graduated from high school; (ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and (iii) Completed 2 years of full-time supervised experience in cytotechnology; or (5)(i) On or before September 1, 1993, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1); and	

(ii) On or before September 1, 1994, have met the requirements in either paragraph (b)(1) or (2) of this section.

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	§493.1485 Standard; Cytotechnologist responsibilities.	
D6165	The cytotechnologist is responsible for documenting-- (a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in §493.1257(d));	
D6166	(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and	
D6167	(c) The number of hours spent examining slides in each 24-hour period.	
D6168	**§493.1487 Condition; Laboratories performing high complexity testing; testing personnel.** The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed. **§493.1489 Standard; Testing personnel qualifications.**	§493.1487 Guidelines: The criteria used to determine the adequacy of the testing personnel involves evaluating testing personnel responsibilities, ensuring that these responsibilities are specified by the director in writing and are appropriate to ensure compliance with the reporting and recordkeeping requirements, quality control monitoring, quality assurance activities, and proficiency testing participation. Cite this deficiency only when problems are found in areas that can be directly related to insufficient numbers of testing personnel. (Use D6101 to relate the finding to insufficient personnel to director responsibilities.) §493.1489 Guidelines: The laboratory director is responsible for ensuring that testing personnel have the appropriate education and experience, and receive the appropriate training for the type

D6170 Each individual performing high complexity testing must--
(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

D6171 (b) Meet on of the following requirements:
(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the appropriate education and experience, and receive the appropriate training for the type and complexity of testing performed. The experience required is clinical in nature. This means examination of and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients, or for providing information to others who will do the diagnosing and treating of the patient's condition. (Use D6101.)

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	laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (2) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution;	Each individual must have documentation of training applicable to the types and complexity of testing performed. This training should be such that the individual can demonstrate that he/she has the skills required for proper performance of preanalytic, analytic, and postanalytic phases of testing. For example, if the individual performs a manual differential, he/she should be able to demonstrate the skills for: o Proper specimen handling prior to testing, e.g., assuring the specimen is properly drawn, if appropriate, properly labelled, the blood film is made within appropriate timeframes and is one-cell layer thick and without cell distortion; o Proper test performance according to the laboratory's policies and manufacturer's instructions, e.g., using stains that are not outdated, that lack contamination and precipitation, following staining procedures, including staining order and timing and allowing slide to air dry, identification of cells and interpretation of smear to be consistent with blood count, diagnosis, treatment; and o Proper reporting of patient test results in accordance with the laboratory's policies, e.g., notifying the person authorized to receive test results of a panic value, not reporting the test result if inconsistent with blood count and noting an explanation, such as "platelet clumping." Training may include, but is not limited to, attendance at: o Seminars given by experts in the field, e.g., a lecture about antibiotic resistance given by the infection control officer of a local hospital; o On-site or off-site instrument trainings given by a manufacturer,e.g., a week-long training course given at the manufacturer's headquarters, or training by a manufacturer's technical representative on an instrument purchased by a laboratory; o Technical training sessions, workshops, or conferences given by a professional laboratory organization, e.g., CAP, ASMT, AACC, ASCT; o Technical education classes or specialty courses that include hands-on test performance, e.g., parasitology, bacteriology, cytology, given by CDC, a State Health Department, or professional laboratory organizations; o A formal laboratory training program; or o Inservices offered by a local hospital laboratory staff, pathologist, or medical technologist to a physician's office personnel. Documentation may consist of, but is not limited to, letters from training programs or employers, attestation statements by the laboratory director, a log sheet initialled by the attendees indicating attendance at a training session/inservice, certificates from organizations providing the training session, workshop, conference, or specialty

course.

§493.1489(b)(1) Guidelines:
See p. C-24 for the definition of and guidance for accredited institutions.
§493.1489(b)(2) Guidelines:
"An associate degree in a laboratory science" is interpreted to mean an associate degree in a chemical or biological science.

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	(3) Have previously qualified or could have qualified as a technologist under 42 CFR 493.1433 published in March 14, 1990 (55 FR 9538), on or before February 28, 1992; (4) Until September 1, 1997-- (i) Have earned a high school diploma or equivalent; and	§493.1489(b)(3) Guidelines The requirements for testing personnel under 42 CFR 493.1433, published March 14, 1990 (55 FR 9538) are as follows: (a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and (b)(1) Have earned a bachelor's degree in medical technology from an accredited college or university. (2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; (3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; (4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses-(i) For those whose training was completed before September 15, 1963. At least 24 semester hours in chemistry and biology courses of which- (A) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and (B) At least 12 semester hours were in biology courses pertinent to the medical sciences; or (ii) For those whose training was completed after September 14, 1963. (A) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry; (B) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and (C) 3 semester hours of mathematics; and (iii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or
D6172	(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-- (A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) The skills required for implementing all standard laboratory procedures; (C) The skills required for performing each test method and for proper instrument use; (D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) A working knowledge of reagent stability and storage;	

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

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	(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality sample values prior to reporting patient test results. On September 1, 1997, must meet the qualifications of §493.1489(b)(1) or (2); (5) For blood gas analysis, the individual must -- (i) Be qualified under §493.1489(b)(1), (2), (3), or (4); (ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (6) For histopathology, tissue examinations must be performed by an individual who meets the qualifications of §493.1449(b) or (l) of this subpart.	(5) With respect to individuals first qualifying before July 1, 1971, the technologist- (i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and (ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or (6) Achieves a satisfactory grade in a proficiency examination approved by HHS. §493.1489(b)(5) Guidelines: This requirement applies only to performance of blood gas analysis procedures which are categorized as high complexity. NOTE: Some blood gas systems have been classified as moderate complexity tests. Therefore, only moderate complexity personnel requirements are applicable to them. Consult the test categorization list published in the Federal Register to confirm the complexity level of testing observed. §493.1489(b)(6) Guidelines: In the case of gross examinations, the technical supervisor may delegate to individuals qualified under §493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately reponsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct onsite supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence of the technical supervisor by individuals qualified under §493.1489 must be reviewed within 24 hours by the technical supervisor. All microscopic tissue examinations must be performed by individuals qualified under §493.1449(b), (l) or (m), as appropriate.
	§493.1495 Standard; Testing personnel responsibilities.	
D6173	The testing personnel are responsible for specimen processing, test performance and for reporting test results.	

D6174 (a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

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D6175	(b) Each individual performing high complexity testing must-- (1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;	
D6176	(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;	
D6177	(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;	
D6178	(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;	
D6179	(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;	§493.1495(b)(5) Guidelines: If, during the survey, testing personnel demonstrate an inability to identify a problem that adversely affects a patient test result, cite 493.1445(e)(12) under the director responsibilities. Some examples of problems that may adversely affect patient test results may include: o A pleural fluid that is mislabeled as a urine specimen and, therefore, is [illegible]

D6181	(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and	cultured as a urine culture; o Performing a potassium on a hemolyzed sample; or o Tests are incubated at 37°C when the manufacturer's instructions require 25°C incubation.

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D6182	(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(4), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.	

D6183 (c) Exception. For individuals qualified under §493.1489(b)(4), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

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D7000	Subpart P - Quality Assurance For Moderate or High Complexity Testing, or Both **§493.1701 Condition: Quality assurance; moderate or high complexity testing, or both.**	§493.1701 Guidelines: Quality assurance (QA) is an ongoing process, encompassing all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. This includes the evaluation of patient preparation and specimen collection, preparation, preservation and transportation (preanalytical), test analysis or examination (analytical) and test result reporting and interpretation (postanalytical). QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other departments of the facility of which it is a part. Policies for prevention of problems must be written as well as communicated to all levels of laboratory personnel. Quality assurance means the laboratory takes an internal look at itself, by those who understand it best, for purposes of removing obstacles to quality patient testing. The laboratory is responsible for developing, directing, monitoring, evaluating, documenting, and communicating its quality assurance program. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves investigation, identification and resolution of the problem and development of policies that will prevent recurrence. The laboratory must monitor, evaluate, and, when appropriate, incorporate the actions taken into the established policies of the prevention mechanism. The laboratory must establish policies and have written procedures for QA assessment including monitoring and evaluation of specimen requirements, collection, handling and processing, corrective action taken in quality control and proficiency testing, employee competency, and result reporting. The laboratory should identify any problem areas. The laboratory should have QA procedures which include such areas of evaluation as: o Gross analysis of specimens, e.g., hemolysis, quantity not sufficient, that would prohibit accurate test results; o Errors in specimen collection, handling, and processing and their effect on the test results; o Steps to evaluate and determine the cause of a control failure; o Policies and timeframes for evaluating employee performance; o Relationship of a particular test result to other tests performed on the same sample; o Timeframes for reporting results; and o The accuracy and reliability of test reporting systems. Use D7001 when you have quality assurance issues that cannot be cited elsewhere in this subpart.
D7001	Each laboratory performing moderate or high complexity test-ing, or both, must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process (pre-analytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards of this subpart as they apply to the services offered, complexity of testing performed, and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.	

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		§493.1701 Probes: Does the laboratory have a QA program which monitors and evaluates the total testing process (preanalytic, analytic, postanalytic)? Does the QA program include all locations/sites where testing is performed? When were policies and procedures last reviewed? Did this review identify any policies or procedures requiring revisions? What actions or remedies does the laboratory take when problems are identified through QA evaluations? How are actions or remedies evaluated for effectiveness?
	§493.1703 Standard; Patient test management assessment.	§493.1703(a) Probes: How does the laboratory monitor and evaluate its criteria for patient preparation and specimen collection and handling? Were the policies and instructions revised, if necessary, as a result of the laboratory's evaluation? How are STAT specimens handled throughout the testing process, e.g., transportation, processing, testing, and reporting?
D7009	The laboratory must have an ongoing mechanism for monitoring	
D7010	and evaluating the systems required under Subpart J, Patient Test Management.	§493.1703(c) Probes: How does the laboratory ensure that its clients have the information necessary to collect and submit specimens acceptable for testing?
	The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:	
D7014	(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;	What system(s) does the laboratory use to assess changes needed in specimen acceptance and rejection criteria?
D7019	(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;	§493.1703(d) Probes: What mechanism does the laboratory have to assess changes needed in test report information or format? How does the laboratory verify the accuracy of the test report information? How is this information correlated with the information received with, and the condition of, the specimen submitted for testing?
D7023	(c) The use and appropriateness of the criteria established for specimen rejection;	
D7025	(d) The completeness, usefulness, and accuracy of the test report information necessary for the interpretation or utilization of test results;	§493.1703(e) Probes: How does the laboratory monitor its established turn-around times and procedures for notification of test results, routine tests, STATS, abnormals or panic values?
D7028	(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and	
D7029	(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.	§493.1703(f) Guidelines: The regulations apply to manual as well as automated reporting systems, i.e., laboratory information systems (LIS). However, the regulations do not specify the mechanism or frequency for which a laboratory should evaluate its test reporting, storage and retrieval system(s). The laboratory must establish its own policies and procedures for evaluating its system(s) and maintain documentation of the evaluation.

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		§493.1703(f) Probes: For LIS: o Has a back-up system (manual or LIS) been established for reporting results when the LIS is down? o How does the back-up reporting system compare to the laboratory's routine reporting system? o Is the laboratory's clerical and technical staff aware of the back-up reporting process and are they capable of using it? How does the laboratory monitor its record storage systems for security, retrivability and confidentiality? If the laboratory uses a report transmitting system, how does it evaluate and monitor whether the transmitted reports are: o Reliable (information accurate, with minimal transmission interference)? o Legible? o Sent to the individual ordering or utilizing test results in a confidential manner? or o Complete with all information expected?
	§493.1705 Standard; Quality control assessment.	§493.1705(a) Probes: How does the laboratory evaluate the actions taken to correct QC problems? Did the actions prevent future testing problems and improve test performance? If not, are additional or other actions instituted? Are policies and procedures revised?
D7033	The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under §493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation.	
D7036	The mechanism must evaluate and review the effectiveness of corrective actions taken for - (a) Problems identified during the evaluation of calibration and control data for each test method;	§493.1705(b) Probes: How does the laboratory monitor and evaluate the reference range for a test methodology? What actions does the laboratory take when a reference range is determined to be inappropriate? Did the actions correct the problem? If not, are additional or other actions instituted?
D7038	(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and	§493.1705(c) Probes: How does the laboratory monitor for errors in reported results? What actions does the laboratory take to correct problems identified with reported results? Did the actions correct the problem or lessen the recurrence of the problem? If not, are additional or other actions instituted?
D7039	(c) Errors detected in reported results.	

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	§493.1707 Standard; Proficiency testing assessment.	493.1707 Probes: How does the laboratory monitor whether corrective actions taken to correct PT failures were successful?
D7040	Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.	When corrective actions were not successful, were other more effective actions instituted?
	§493.1709 Standard; Comparison of test results.	
D7043	(a)If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.	§493.1709 Probes: How does the laboratory monitor and evaluate all methods for the same tests done at multiple locations or on different instruments, e.g., split or "blind" sample testing of materials with known values?
D7047	(b)If a laboratory performs tests that are not included under Subpart I, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year.	How does a laboratory verify accuracy of the test results of analytes not included in the regulated analytes for proficiency testing (Subpart I), e.g., split or "blind" sample testing of materials with known values, external assessment program?
	§493.1711 Standard; Relationship of patient information to patients test results.	
D7050	For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as -	§493.1711 Probes: What system(s) are in place to identify inconsistent patient test results? What mechanism has the laboratory established for evaluating test results with patient information?
D7051	(a) Patient age; (b) Sex;	
D7052	(c) Diagnosis or pertinent clinical data, when provided;	How does the laboratory obtain sufficient information to enable an evaluation of test results with clinically relevant patient information?
D7053	(d) Distribution of patient test results when available; and	When test results do not correlate with patient information, e.g., age, sex, submitted diagnosis, what actions are taken by the laboratory to confirm test results or patient information?

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D7054	(e) Relationship with other test parameters, when available within the laboratory.	
	§493.1713 Standard; Personnel assessment.	§493.1713 Probes: How does the laboratory evaluate the competency of its employees? When problems are identified, what corrective actions are instituted to assist employees to improve performance? How frequently are personnel policies and procedures evaluated for effectiveness? How does the laboratory assure that an individual who had problems in performance is competent after appropriate training and technical assistance is completed? How does the laboratory evaluate personnel for consistency in slide review, e.g., ANA, manual differential, urine sediment?
D7055	The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.	
	§493.1715 Standard; Communications.	§493.1715 Guidelines: Communication begins with the test request or information requested on patient specimens. If the information provided to clients on patient preparation and specimen handling is confusing, the individuals involved in collecting and transporting specimens may not furnish the laboratory with the appropriate specimen or patient information needed to perform the tests. The test report form should be easily understood and accurately portray patient test results, normal or clinical reference values and other information necessary for interpreting test results.
D7057	The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations.	§493.1715 Probes: How often does the laboratory evaluate the mechanism for requesting STAT test results to ensure that the laboratory receives the STAT request in a timely manner? How does the laboratory assess whether its patient test management policies and criteria (specimen requisitions, patient preparation and specimen collection instructions), evaluated under §493.1703(b) are understood and followed by clients submitting specimens?
D7058	Corrective actions must be taken, as necessary, to resolve the problems and minimize communications breakdowns.	What actions does the laboratory take if specimens received from one client are consistently unsatisfactory for testing? How does the laboratory assess whether its report forms evaluated under §493.1703(d) are conveying the necessary information for interpretation and diagnosis? What actions does the laboratory take if test requisitions from one or more clients are consistently incomplete, i.e., missing requested information?

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	§493.1717 Standard; Complaint investigations.	§493.1717 Probes: How does the laboratory document all complaints received and determine which complaints require investigation and which do not? (Investigation of complaints must be documented and, if a problem is identified, corrective action and resolution must be documented, with ongoing monitoring to minimize recurrences.)
D7059	The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented.	
D7060	Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.	
	§493.1719 Standard; Quality assurance review with staff.	§493.1719 Guidelines: "Quality assurance reviews" refers to all QA activities performed and documented by the laboratory. All pertinent information must be shared with the laboratory staff as well as with other appropriate departments.
D7062	The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff.	§493.1719 Probes: How is the laboratory staff involved and/or informed of the outcome of QA reviews? On an overall basis, is the recurrence of problems minimized to prevent a threat to patient health and safety and improve the quality of test results?
D7065	The laboratory must take corrective actions that are necessary to prevent recurrences.	
	§493.1721 Standard; Quality assurance records.	§493.1721 Guidelines: Do not expect QA records to be maintained and stored in one location. The records may be stored in the specific area or department appropriate to the monitoring and evaluation of the laboratory activities (preanalytical, analytical and postanalytical)
D7066	The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken.	§493.1721 Probes: What records does the laboratory have to document QA activities performed? Are corrective actions documented?
D7067	All quality assurance records must be available to HHS and maintained for a period of 2 years.	

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	Subpart Q – Inspection	§493.1775 Guidelines: In any laboratory holding a CLIA certificate, tests listed on the waived list in §493.15(c) are not subject to routine surveys. A survey for waived tests may be conducted only when authorized by the RO in the following instances: o To collect information on waived tests; o If a complaint is alleged, or o You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results. When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, Subpart A, and §§493.35, 493.37 and 493.39, Subpart B, of these guidelines. Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver. Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accomodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, i.e., physicians' offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.
D8000	**§493.1775 Condition: Inspection of laboratories issued a certificate of waiver.** (a) HHS or its designee may conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to assess compliance with the applicable requirements of part 493.	
D8001	(b) The laboratory may be required, as part of this inspection, to- (1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;	
D8002	(2) Permit HHS or its designee access to all areas of the facility including- (i) Specimen procurement and processing areas; (ii) Storage facilities for specimens, reagents, supplies, records, and reports; and (iii) Testing and reporting areas.	
D8003	(3) Permit employees to be observed performing tests, data analysis and reporting;	
D8004	(4) Permit HHS or its designee upon request to review all information and data necessary to (i) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;	
D8005	(ii) Evaluate complaints from the public;	§493.1775(b)(4)(iii) Guidelines: When a laboratory has failed to obtain a registration certificate before performing and reporting patient results for tests not listed in §493.15, cite D1000 on the HCFA-2567 and solicit a Plan of Correction. Notify the RO of a possible action by the OIG if the laboratory does not obtain the appropriate certificate or cease non-waived testing.
D8006	(iii) Determine whether the laboratory is performing tests not listed in §493.15; and	

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D8007	(iv) Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.15; and	
D8008	(5) Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.	
D8009	(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493.	
D8044	(d) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke laboratory's CLIA certificate of waiver in accordance with subpart R of this part **§493.1776 Condition: Inspection of physician-performed microscopy procedures.** (a)HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to-- (1)Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health; (2)Evaluate complaints from the public; (3)Determine whether the laboratory is performing tests in addition to procedures listed in §493.16 that are not included on the laboratory's certificate; and	§493.1775(d) Guidelines: If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken: o Explain your authority under §493.35(d), the facility's agreement to allow HHS to conduct the survey and the consequences of failure to permit a survey; and o If necessary, consult with your supervisor or the RO.

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	(4)Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.16. Applicable requirements for the purpose of this section are located in subpart C, registration certificate, certificate for physician-performed microscopy procedures, and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; and subpart P, quality assurance of this part, as well as §493.16(e).	
D8045	(b)The laboratory may be required, as part of this inspection, to--(1)Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493 as noted in paragraph (e) of this section;	
D8046	(2)Permit HHS or its designee access to all areas of the facility including-- (i)Specimen processing areas; (ii)Storage facilities for specimens, requests, supplies, records, and reports; and (iii)Testing and reporting areas.	
D8047	(3)Permit physicians to be observed performing tests and reporting results;	
D8048	(4)Permit HHS or its designee upon request to review all information and data necessary to-- (i)Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serous risk to public health;	

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D8049	(ii)Evaluate complaints from the public;	
D8050	(iii)Determine whether the laboratory is performing tests in addition to procedures listed in §493.16 that are not included on the laboratory's certificate;	
D8051	(iv)Collect information to determine the addition, deletion, or continued inclusion of tests listed in §493.16; and	
D8052	(5)Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.	
D8053	(c)The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493. (d)Failure to permit an inspection under this subsection may result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R of this part.	
D8011	**§493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver, certificate for physician-performed microscopy procedures, or a certificate of accreditation.** (a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory	§493.1777 Guidelines: For initial certification, including addition of specialties/subspecialties or non-waived tests, recertification, and relocation surveys where unannounced inspections could disrupt patient care, or when laboratory personnel will not be available, conduct surveys on an announced basis. The above exception does not apply to complaint and revisit surveys, which are to be conducted only on an unannounced basis. The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled survey date. Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

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	possessing a registration certificate before issuance of a certificate.	Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.
D8012	(b) The laboratory may be required, as part of this inspection, to--	Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physicians' offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.
	(1) Test samples (including proficiency testing samples) or perform procedures as HHS or its designee requires;	
D8013	(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;	
D8014	(3) Permit employees to be observed performing tests (including proficiency testing specimens), data analysis and reporting;	§§493.1777(c)-(e) Guideline: The regulations do not require a laboratory to maintain records on-site. During the survey, the laboratory must be able to retrieve copies of all records and necessary information upon request. Determine what constitutes a reasonable timeframe based on the information requested.
D8015	(4) Permit HHS or its designee access to all areas of the facility including-	§§493.1777(d)(1) and (3) Guideline: When citing quality control documentation deficiencies for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D6072.
	(i) Specimen procurement and processing areas;	
	(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and	§493.1777(d)(1) Guideline: When citing quality control record retention requirements for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D8021. For all other tests, use D4182, D4184, D4185, as appropriate.
	(iii) Testing and reporting areas; and	
D8019	(5) Provide copies to HHS or its designee of all records and data it requires.	
D8020	(c) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.	Cite patient test record retention requirements at D3035. Cite quality assurance documentation deficiencies at D7066.
	(d) The laboratory must retain-	
D8021	(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;	

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	(2) Pathology test reports for at least 10 years after the date of reporting as required in §493.1109; and	§493.1777(d)(2) Guideline: Cite patient test record retention requirement at D3049.
D8023	(3) All other laboratory records for at least 2 years.	§493.1777(d)(3) Guideline: When citing quality control record retention requirements for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D8023. For all other tests, use D4182 for quality control record retention requirements.
D8024	(e) The laboratory must provide upon request all information and data needed by HHS or its designee to make a determination of the laboratory's compliance with the applicable requirements of part 493. f) HHS or its designee may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results. (g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R.	Cite proficiency testing record retention requirements at D2015. Cite patient test management record retention requirements at D3034. Cite quality assurance documentation deficiencies at D7066. §493.1777(g) Guideline: If for any reason a facility denies entry to or does not permit you to conduct a survey, take the following steps: o Explain your authority under §493.35(d), the facility's agreement to allow HHS to conduct the survey and the consequences of failure to permit a survey; and o If necessary, consult with your supervisor or the RO. If the laboratory continues to refuse a survey refer to Subpart R - Enforcement Procedures and the Adverse Action procedures beginning at §6300 of the SOM.
D8027	**§493.1780 Condition: Inspection of accredited and CLIA-exempt laboratories.** (a) HHS or its designee may conduct unannounced or announced, random validation inspections of any accredited or CLIA-exempt laboratory at any time during its hours of operation.	§493.1780(a) Guideline: Validation surveys of accredited laboratories will be conducted by the State survey agencies. Refer to special procedures for accredited laboratories beginning at §6600 of the SOM. The RO is responsible for conducting validations of CLIA-exempt laboratories.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D8028	(b) HHS or its designee will conduct unannounced complaint inspections of an accredited or CLIA-exempt laboratory at any time during its hours of operation upon receiving a complaint about that laboratory.	
D8029	(c) The laboratory may be required, as part of either of the above inspections, to- (1) Test samples (including proficiency testing samples) or perform procedures as required by HHS or its designee;	
D8030	(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;	
D8031	(3) Permit employees to be observed performing tests (including proficiency testing specimens), and performing data analysis and reporting activities; and	
D8032	(4) Permit HHS or its designee access to all areas of the facility including-- (i) Specimen procurement and processing areas; (ii) Storage facilities for specimens, reagents, supplies, records, and reports; and (iii) Testing and reporting areas; and	
D8036	(5) Provide copies to HHS of all records and data required under these requirements.	
D8037	(d) The laboratory must have all records and data accessible and retrievable within a reasonable time during the inspection.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
D8038	(e) The laboratory must retain-- (1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;	§§493.1780(e)(1) and (3) Guideline: When citing quality control documentation deficiencies for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D6072.
D8039	(2) Records of blood and blood product testing for a period of not less than 5 years after processing records have been completed, or 6 months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d); (3)Pathology test reports for at least 10 years after the date of reporting, as required in §493.1109; and	§493.1780(e)(1) Guideline: When citing quality control record retention requirements for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D8038. For all other tests, use D4182, D4184, D4185, as appropriate. Cite patient test record retention requirements at D3035. Cite quality assurance documentation deficiencies at D7066.
D8041	(4) All other laboratory records for at least 2 years unless otherwise specified in part 493.	§493.1780(e)(2) Guideline: Cite patient test record retention requirement at D3049.
D8042	(f) The laboratory must provide, upon request, all information and data needed by HHS to make a determination of compliance or noncompliance with the applicable requirements of part 493. (g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's Medicare and Medicaid approval for payment; and suspension of or action to revoke the laboratory's CLIA certificate of accreditation in accordance with subpart R of this part.	§493.1780(e)(3) Guideline: When citing quality control record retention requirements for all devices, products, or test systems cleared or approved by the FDA that are moderately complex and have not been modified by the laboratory, use D8041. For all other tests, use D4182 for quality control record retention requirements. Cite proficiency testing record retention requirements at D2015. Cite patient test management record retention requirements at D3034. Cite quality assurance documentation deficiencies at D7066.

I. BLOOD BANKS AND TRANSFUSION SERVICES

HCFA and the Food and Drug Administration (FDA) have a Memorandum of Understanding (MOU) to define the survey activities for facilities performing immunohematology (bloodbank) testing and transfusion services that are subject to both HCFA (CLIA) and FDA regulations. The purpose of the MOU is to reduce duplicative survey activities between the two agencies. HCFA is responsible for inspecting approximately 4500 transfusion service facilities and reference laboratories formerly inspected by FDA and recording findings relative to FDA regulations for laboratory testing done relative to donor screening and product preparation.

A. Facilities Surveyed By The State Agency (SA)--Survey those facilities performing any immunohematology testing, including hospitals, clinics, physician office laboratories, or donor centers as well as reference laboratories. Use the Blood Bank Inspection Checklist and Report (HCFA-282) in addition to all other required survey forms to record survey findings of FDA requirements in applicable facilities.

FDA continues to inspect hospital transfusion services and reference laboratories covered under CLIA for donor purposes if they:

o Collect blood and blood components in other than emergency situations, including autologous donations;

o Perform therapeutic collection or pheresis and the resulting product is used for further manufacture; or

o Prepare frozen, deglycerolized, washed, rejuvenated, or leukocyte-poor red blood cells and/or recovered human plasma.

Facilities performing services listed above which include transfusion services may be subject to dual inspections by you for CLIA and by FDA. There are approximately 2,800 facilities which routinely perform blood collection, blood processing (except red cell packing) and blood storage and distribution in addition to providing transfusion services. Those facilities performing bloodbanking or transfusion services which are unaccredited are surveyed by both you and FDA. In these instances, perform a CLIA survey relative to patient testing and incorporate the applicable FDA requirements included in the HCFA-282 for compatibility testing, transfusion reactions, storage and distribution and laboratory testing (Parts B, H, and I), while FDA inspects for its blood collection, processing and shipping requirements relative to donor testing in these facilities. Because FDA requirements and CLIA regulations partially overlap, but do not completely coincide, relative to tests done for patient and donor testing, it is unnecessary to duplicate the inspection of these particular requirements covered by FDA for donor testing.

Facilities performing services which do not include transfusion services, but are performing laboratory testing for purposes of making a product, must comply with both FDA and CLIA regulations. FDA conducts its portion of inspections in those facilities while HCFA surveys those facilities for compliance with the CLIA regulations.

1. Deemed Status.--Do not survey under the Federal program those facilities accredited by organizations which have been granted deemed status by HCFA unless their accreditation is lost, or they are inspected as part of a validation or complaint survey. (Accredited facilities may still be routinely surveyed by FDA under its statutory and regulatory requirements.)

2. Personnel and Proficiency Testing (PT).--FDA does not have specific PT requirements and the personnel standards are different as specified under 21 CFR 606.20. FDA does not apply the CLIA standards to facilities under its sole jurisdiction. However, all facilities doing testing whether for patient purposes or for donor purposes fall under CLIA and are subject to the CLIA personnel and PT standards. Continue to monitor PT.

3. Quality Control and Management.--The appropriate CLIA regulations for moderate and/or high complexity testing apply to all facilities that are certified under CLIA. The FDA requirements are a supplement to, and not a replacement for, the existing requirements.

B. HIV, Hepatitis, and Syphilis Testing.--HCFA is responsible for the survey and certification of reference laboratories performing HIV, hepatitis, and syphilis testing for registered, unlicensed blood establishments even though these laboratories are subject to FDA regulations. For these facilities, testing for HIV antibody (§493,1241(d)(1)), hepatitis B surface antigen (§493.1241(d)(2)) and syphilis (§493.1239(e)) for purposes of blood product preparation must meet all requirements for CLIA certification as well as FDA requirements.

Below are the relevant portions of the FDA's requirements cross-referenced to CLIA for immunohematological, HIV, hepatitis, and syphilis testing:

	FDA	HCFA (CLIA)
Immunohematological Testing	21 CFR 606	42 CFR 493.1273
	21 CFR 610.53 21 CFR 640, subparts A,B,C,D and F	Use D4475
HIV	21 CFR 610.45	42 CFR 493.1241(d)(1) Use D4277
Hepatitis Testing	21 CFR 610.40	42 CFR 493.1241(d)(2) Use D4278
Syphilis Testing	21 CFR 640.5(a)	42 CFR 493.1239(e) Use D4270

The HIV, hepatitis and syphilis testing requirements above do not require transfusion service facilities to retest blood for HIV, hepatitis and syphilis if the blood has already been tested in another CLIA-certified facility.

II. SURVEYS OF BLOOD BANKS AND TRANSFUSION SERVICES

A. List of Facilities to be Surveyed.--Obtain lists of facilities to be surveyed from the RO. Address questions concerning any facilities on the list to the RO.

B. Survey Reports.--Use HCFA-1557, Laboratory Survey Report Form and HCFA-209, Laboratory Personnel Report, the HCFA-282, Blood Bank Inspection Checklist and Report, and the HCFA-2567, Statement of Deficiencies and Plan of Correction for all laboratories. For laboratories in hospitals, use the applicable portions of the HCFA-1537, Hospital Survey Report Form.

C. Guidelines.--Use the FDA guidelines appearing in the instruction booklet for FDA-2609 (HCFA-282), Exhibit 123 of the SOM, in conjunction with the surveyor guidelines for immunohematology, transfusion services and blood banking.

D. Completing the HCFA-282.--The HCFA-282 is used to document compliance with the applicable FDA regulations for blood banks, reference laboratories and transfusion services during the course of a survey for CLIA compliance. This would usually be parts B, H, and I which involve the ABO, Rh and viral testing of blood components, along with compatibility testing, transfusion reactions and storage/distribution.

The HCFA-282 has a space for Yes or No only responses and does not contain a column for "not applicable" (N/A) responses. If a question on this form requires an N/A response, write N/A in the Yes/No box for that question. If an entire section (A, B, or C) of this form is N/A, note this on the cover sheet in the "Operations" section.

All questions on the first page must be answered, if applicable. Make entries in the comments section as necessary. Write the facility name and CLIA certification number at the top of each page to ensure that separated pages can still be identified. Attach the HCFA-282 to the other survey forms used.

E. Duplicative Regulations.--FDA and HCFA regulations contain a number of duplicative requirements or statements, e.g., recordkeeping, expired reagents, and calibration of equipment. In some instances, FDA regulations may be repetitive in their general phrasing as compared to HCFA regulations.

However, FDA has several specific requirements and any deficiencies noted in its regulations are, if possible, to be related to the HCFA regulations and cited as such. If this is not possible, bring the deficiency to the attention of the FDA office for handling. (These reference citations are printed on the HCFA-282.)

F. Fatal Transfusion Reactions.--Send the RO reports of fatal transfusion reactions identified during a facility survey or obtained on the basis of a complaint investigation. These reports are used to ensure that the facilities have properly notified FDA of fatal transfusion reactions and that all necessary followups have been conducted by both HCFA and FDA. (See 21 CFR 606.170.)

If you learn of a transfusion fatality which has not been reported to FDA, notify the facility that such reporting is mandatory and to immediately report the fatality by telephone to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance
(301) 295-8191

Simultaneously notify the RO of the fatality. The RO notifies CO.

G. Notification of Blood Banking Activities Subject to Registration Under §510 of the Federal Food, Drug, and Cosmetic Act.--If, during the survey, a firm is found to be performing any activity requiring FDA registration, have it show you its current copy of form FDA-2830, "Blood Establishment Registration and Product Listing." Activities requiring registration with FDA include:

- o Routine homologous, directed or autologous blood collection;
- o Preparation of frozen, deglycerolized, washed, rejuvenated, or leukocyte-poor red blood cells; and
- o Manual and/or automated blood component manufacture.

If no form exists, or the form has not been validated in the upper right corner, i.e., "Received Food and Drug Administration," followed by a date within one year of the survey date, assume that the firm is not currently registered. Request that the firm make a photocopy of the form (if it has one), annotating it to denote those products it is manufacturing, e.g., "Red Blood Cells Leukocytes Removed," and return the form to:

Food and Drug Administration
Center for Biologics Evaluation and Research
8800 Rockville Pike - HFB-240
Bethesda, MD 20892
(Telephone 301-295-8434)

This address is also on the blue copy of the validated FDA 2830 mailed to the reporting official's mailing address.

If the firm is unable to locate any registration form or provide a current, validated form, notify the RO, which in turn will inform CO, which will forward a copy of the applicable pages of the blood bank checklist or survey form to FDA noting the facility's name and products being manufactured, e.g., "Red Blood Cells Leukocytes Removed." FDA will then contact the facility.

If the most recent form is marked "EXEMPT," followed by the date and "FOOD AND DRUG ADMINISTRATION," the firm does not need to register.

III. INVESTIGATION OF TRANSFUSION-RELATED FATALITIES

The provisions of 21 CFR 606.170(b) require that complications of blood collection or transfusion confirmed to be fatal be reported to FDA. FDA evaluates these reports and may undertake special investigations to determine whether remedial action has been or needs to be undertaken by the blood establishment.

Under the provisions of the MOU between HCFA and FDA, reports that FDA receives concerning transfusion related fatalities in CLIA-certified facilities are forwarded to HCFA, if necessary, for further evaluation and follow-up investigation.

The RO may forward transfusion-related fatality incidents to you for investigation. The objectives of the investigation are to assure that the facility has taken appropriate follow-up action to verify the accuracy of the reported facts surrounding the event, and to identify and correct any problems related to transfusion services. The facility is not considered to be in compliance unless all corrective actions have been instituted to prevent recurrence of fatal transfusion reactions.

Investigations of transfusion-related fatalities are conducted by you and/or the RO directly, regardless of whether the facility is accredited or whether the laboratory and blood bank are accredited.

Under §493.1285, Investigation of transfusion reactions, CLIA's investigational jurisdiction is limited to those areas of the facility performing testing relative to transfusion. Under the applicable Medicare facility requirements, an investigation of a fatality may include a review of all policies and procedures within a facility to assure that they are adequate to ensure the safety of individuals being transfused within that facility.

Historically, fatalities have occurred primarily in hospital settings. This does not preclude their occurrence in other health care settings such as nursing homes, dialysis units, HMOs or even patients' homes through a home health agency (HHA). CLIA is directed towards laboratories. Problems leading to the fatality under investigation may not be limited to the laboratory and often involve other areas of the facility, e.g., nursing services, OR, ER. Conduct a survey using the CLIA regulations and those regulations applicable to the facility involved. Applicable surveyor personnel would also need consideration. The guidelines following this section outline the investigation of a transfusion-related fatality in a hospital. They are an example to you of how to perform an investigation in a hospital setting. In addition to the A tags used to report hospital deficiencies that may be noted during the fatality investigation, there are examples of the most closely corresponding tags for long-term care facilities (F), tags for HHAs (G) and tags for ESRD facilities (V).

A. Scheduling the Investigation.--The RO will schedule or notify you to schedule a survey within 45 days of receipt of the request from CO and notify the facility or laboratory of the survey date if the facility filed the report of death to FDA. The facility is aware of the possibility of a follow-up. If the report of the fatality originated with any other source, conduct an unannounced survey. See pages C-277 - C-278 for further instructions on conducting a transfusion service investigation.

B. Documenting Deficiencies.--Assess the institution's compliance with applicable Conditions/Standards during the onsite review. The review may warrant investigation of departments outside the laboratory, i.e., OR, ER, nursing services, medical records, to ascertain problems which may have led to the fatality. Complete the applicable portions of the HCFA-282, HCFA-1557 and other applicable survey forms such as the HCFA-1537. A sample of the HCFA-282 and the corresponding instructions on how to complete it are found at Exhibit 123 of the SOM. Prepare a HCFA-2567 to document deficiencies identified during the onsite review.

C. Exit Conference.--Conduct an Exit Conference to inform the facility of your observations and findings at the conclusion of the survey. Although it is HCFA's general policy to conduct an Exit Conference, be aware of situations that would justify refusal to conduct or to continue an Exit Conference. See §6160 of the SOM.

D. Report of Investigation.--Prepare a detailed narrative investigation report including:

- Date of investigation;
- Identification of the fatality by the institution's medical record or other identification number;
- Name, titles, and professional credentials of the investigation team;
- Names and titles of all individuals interviewed, and job functions of each, where appropriate;

- A list of all records and other documents reviewed. Identify any records and documents which could not be located;
- Completed survey reports;
- Conclusions concerning the cause of the fatality, accuracy of the facility's fatality report to FDA, and adequacy of institutional follow-up measures;
- Recommendations which the team feels should be communicated to the institution;
- Copies of records and documents obtained from the institution; and
- The HCFA-2567 with POC.

Do not provide the facility with the HCFA-2567 until it has been reviewed and approved by the RO.

Forward the report of the investigation, including all survey forms and completed POCs to the RO for review and transmission to CO. CO expects the report within 60 days of the investigation. If the RO agrees with your recommendations, it forwards them to the facility. CO forwards the report to FDA and determines in conjunction with the RO what, if any, follow-up action is required. CO coordinates with appropriate accrediting bodies.

INTERPRETIVE GUIDELINES - LABORATORIES
INVESTIGATION OF TRANSFUSION-RELATED FATALITIES

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A011	**§482.11 Condition of participation: Compliance with Federal, State and local laws.**	§482.11 Guidelines: The blood bank must meet the applicable licensure and/or registration requirements of the FDA and of the States for the transfusion of blood and blood products. Verify that the blood bank has the current licensure and/or registration. If you are uncertain as to the Federal (FDA) license and/or registration required, consult with the RO.
A012	(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.	
A016	**§482.12 Condition of participation: Governing body.** The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this Part that pertain to the governing body.	§482.12 Guidelines: The governing body must approve the established procedure(s) to investigate suspected transfusion reactions. If transfusion reactions have occurred, investigations must be conducted by the facility or under arrangement in accordance with the facility's established policy. Transfusion reactions, including any possible transfusion related fatality cases, should be identified and the cause of the transfusion reaction determined to the extent possible in accordance with the facility's established procedures. The governing body must review any medical staff recommendations for preventing future transfusion reactions.
A017	(a) Standard: Medical staff. The governing body must:	§482.12 Probes: How does the governing body implement the recommendations of the medical staff, such as changing policies and procedures, providing appropriate staff training, or disciplining the staff members responsible for the transfusion reaction? What type of documentation, e.g., minutes of the governing body meetings, does the facility have to demonstrate the liaison/communication between the governing body and the medical staff?
A022	(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;	
A026	(c) Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:	

A030 (4) A doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that--
(i) is present on admission or develops during hospitalization; and

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine or optometry, or a chiropractor, as that scope is-- (A) Defined by the medical staff; (B) Permitted by State law; and (C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.	
A044	(e) Standard: Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for contracted services.	§482.12(e) Guidelines: The hospital must have a list of facilities providing blood and blood products and immunohematologic testing (including follow-up testing and investigation of transfusion reaction) if not provided directly by the hospital. All testing must be performed in a CLIA-certified facility. Refer to pA146. §482.12(e) Probe: How and when was the blood transfusion service notified of the suspected transfusion reaction fatality? What is the hospital's policy for notifying the contracted laboratory or blood service of the suspected transfusion reaction?
A045	(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.	
A046	(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.	
A050	**§482.21 Condition of participation: Quality Assurance.** The governing body must ensure that there is an effective, hospital-wide, quality assurance program to evaluate the provision of patient care.	§482.21 Guidelines: When surveying hospital quality assurance, laboratory quality assurance (42 CFR Part 493, Subpart P) is only a section of the hospital-wide program. The investigation of a transfusion reaction must include all departments of the hospital that are involved in the transfusion process.
A051	(a) Standard: Clinical plan. The organized, hospital-wide quality assurance program must be on-going and have a written plan of implementation.	Nearly all fatal transfusion reactions occur because ABO incompatible blood was inadvertently administered to the patient. Both the laboratory personnel who collect, test and issue the blood and the clinical staff who receive and administer the unit have responsibility for correctly identifying the patient and blood and blood product. Many occur because clinical staff do not recognize the signs of a transfusion reaction, immediate and delayed, and do not discontinue the administration of the blood or blood product pending a transfusion reaction work-up.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A052	(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.	§482.21 Probes: How does the governing body ensure effective communication between themselves and the medical staff?
A054	(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.	How has the hospital assured that all personnel on all shifts in all departments (including nursing, medical staff) understand and are knowledgeable about the hospital's current policy for administering blood and blood products? How is this documented? How does the hospital's quality assurance program ensure effective interdepartmental communication to assure that each department's transfusion policies and procedures are consistent?
A058	(c) Standard: Implementation. The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.	When changes are made in transfusion service policies and procedures, how and when are the changes communicated to the hospital staff of each ward or service unit? Are policies and procedures readily accessible to staff? How does the facility assure that all possible cases of transfusion reactions are identified? How does the facility ensure that each transfusion reaction investigation is conducted in a timely, uniform and consistent manner in accordance with the hospital's established policies and procedures? How has the hospital implemented and monitored any remedial action taken as a result of
A059	**§482.22 Condition of participation: Medical staff.** The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.	§482.22 Guidelines: The medical staff has the primary responsibility for assessing the treatment needs of patients and for developing a plan of care for each patient. The physician must evaluate and document the need for blood transfusions. In accordance with hospital policies, the physician may assist in the investigation of suspected transfusion reactions and provide supportive care throughout the patient's clinical course.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Review: o The medical record to determine whether the patient's medical care and treatment are documented; o The physician's orders and/or interview the physician to determine whether appropriate steps were taken to analyze the transfusion reaction; o Any documentation of a possible transfusion reaction to determine that appropriate laboratory tests were ordered; and o The minutes of the medical staff committee meetings or other available documentation to determine whether the medical staff: - Assessed the transfusion reaction's contribution to the death; - Evaluated the patient's transfusion status and underlying disease; - Analyzed the risk factors contributing to the error; and - Made recommendations to the governing body and/or other staff to prevent reoccurrence.
A075	**§482.23 Condition of participation: Nursing services.** The hospital must have an organized nursing service that provides 24-hour services. The nursing services must be furnished or supervised by a registered nurse.	§482.23 Guidelines: Determine if the appropriate type and number of nursing staff were on duty when any suspected fatal transfusion or other transfusion reaction occurred.
A076	(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.	
A077	(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.	
A087	(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted	§482.23(c) Guidelines: Nursing service blood transfusion policies and procedures must be complete and provide standardized instructions for ordering blood, obtaining blood and blood products from the laboratory (release and return procedure), identifying the patient, administering blood and blood products and identifying and responding to transfusion reactions in a timely manner.
A088	(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws, and regulations including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.	All persons who administer blood and blood products must receive the necessary training and be familiar with and follow the hospital's approved policies and procedures. Interview the staff (nursing, clerical, or other personnel who have handled the blood) to determine adherence to the hospital's blood transfusion policies and procedures.
A089	(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under §482.12(c). When telephone or oral orders must be used, they	If blood cell hemolysis occurred during the transfusion, ascertain whether: o Any other fluids were administered during the transfusion in the same arm and whether saline or other media were used; o If saline was used, was a "Y" type infusion set used?; o The proper gauge of needle was used for the transfusion, as prescribed in the

A090 (i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures consistent with Federal and State law;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A091	(ii) Signed or initialed by the prescribing practitioner as soon as possible, and	
A092	(iii) Used infrequently	
A093	(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.	
A094	(4) There must be a hospital procedure for reporting transfusion reactions, drug reactions and errors in administrations of drugs.	
A095	**§482.24 Condition of participation: Medical record services.** The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.	§482.24 Guidelines: The medical record documents, summarizes and evaluates the medical care furnished to the patient. In addition, the medical record documents the communication between the physician and other professional staff providing for the patient's care. It also contains the major portion of the background information needed to investigate suspected transfusion reactions. All clinical information pertaining to the patient must be incorporated into the medical record. This includes a description of the patient's condition as well as a record of the diagnostic and therapeutic procedures performed and the patient's response to treatment. Review the medical records for clerical errors and for factors contributing to the suspected transfusion reaction and/or patient's death.
A101	(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress, and response to medications and services.	
A102	(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing or evaluating the service furnished.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A103	(i) The author of each entry must be identified and must authenticate his or her entry.	
A104	(ii) Authentication may include signatures, written initials or computer entry.	
A105	(2) All records must document the following as appropriate:	§482.24(c)(2) Guidelines: The medical records must contain sufficient information to justify the diagnosis and warrant the treatment and care provided to patients. Medical records must be complete and include: o Patient identification, including the patient's name, date of birth, address and other pertinent demographic data. Each patient must have a unique patient identifier that describes the patient and his/her medical record; o Medical and family history, including the reason for admission, details of present and past illnesses and any pertinent family disease history; o Physical examination documenting the physician's assessment of the patient's current health status; o Provisional diagnosis; o Diagnostic and therapeutic orders written by the physician and carried out by qualified staff. Orders must contain a specific request or physician order for type and screen or compatibility testing, number of units, type of blood product to be transfused, and specific order for transfusion administration, including timeframe to be administered; o Orders that include investigative and therapeutic procedures to be carried out when a transfusion reaction was suspected; o Therapeutic orders appropriate to the patient's underlying illness and current symptomatology; o Clinical observations or patient progress notes which present a chronological description of the patient's hospital course, including indication for a blood transfusion. These records should reflect changes in the patient's condition as well as results of treatment, including reactions; o Nursing notes containing pertinent, meaningful observations and information to help identify transfusion reactions. Nursing notes should document: - Early symptoms of transfusion reaction, i.e., urticaria, dyspnea, cyanosis; - Symptoms indicating reaction to incompatible blood, e.g., fullness in head, severe pain in back, sensation of constriction in chest, increased pulse, drop in blood pressure, nausea and vomiting; - Symptoms of hematuria, diminishing urine output, shock, and/or other symptoms of renal failure; - Possible pyrogenic reaction to a blood transfusion, including fever, chills, headache, nausea, vomiting, weakness and lumbar pain;
A106	(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.	
A107	(ii) Admitting diagnosis.	
A108	(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.	
A109	(vi) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.	
A110	(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal, or State law if applicable, to require written patient consent.	
A111	(vi) All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.	
A112	(vii) Discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care.	

A113 (viii) Final diagnosis with completion of medical records within thirty days following discharge.

- The volume of blood transfused; and
- Monitoring of vital signs (pre-transfusion and post-transfusion);

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		o Clinical laboratory, tissue and X-ray reports, diagnostic test reports, and results of the crossmatch. Review transfusion sheet for appropriate comparison of patient identification information with information on crossmatch reports and the unit. Note whether two persons checked the unit and signed the form. Review operative reports and anesthesia records for the administration of intraoperative blood transfusions; o Discharge summary sheets that provide a chronological recapitulation of the medical history of the patient, including final diagnosis, procedures performed, treatment rendered, and the results leading to the death, as well as results of treatment given (including records of transfusion reactions); o The autopsy report, if an autopsy was performed. Examine the record to determine if there are any inconsistencies with the reported cause of death; o Reports of consultations provided during the patient's hospitalization and course of treatment; and o The reports in the medical record. Compare these with the information supplied to the Center for Biologics Evaluation and Research of FDA. A copy of this material is included in the request by HCFA CO to the RO to perform an investigation.
A145	**§482.27 Condition of participation: Laboratory services.** (a) General. The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.	§482.27 Guidelines: See Appendix C.
A146	(b) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a laboratory, that meets the requirements of part 493 of this chapter.	§482.27(b)(1) and (2) Guidelines: See Appendix C.
A147	(1) Emergency laboratory services must be available 24 hours a day.	
A148	(2) A written description of services provided must be available to the medical staff.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Subpart H: Participation in Proficiency Testing The laboratory meets all of the proficiency testing requirements specified in §493.801 through §493.865	Guidelines: See Appendix C, §§493.801 through 493.807 and §§493.857 through 493.865. Determine if there have been any proficiency testing failures in immunohematology, particularly for the time period when the death occurred. If it is suspected that there was laboratory error or poor performance, arrange to bring on-site proficiency testing samples to assess staff performance particularly the performance of those individuals suspected of making the errors. See §§493.859-493.861 or §§493.863-493.865.
	Subpart J: Patient Test Management The laboratory meets all of the requirements specified in §493.1101 through §493.1111.	Guidelines: See Appendix C, §§493.1101-493.1111. Records must be available for five years (unless required for a longer period under State or local law), in accordance with §493.1107. Probes: How has the laboratory assured patient identity at the time of specimen collection, specimen processing, compatibility testing, the issue and the administration of blood and blood products? See §493.1103(a) or §493.1273(d). How does the laboratory report immunohematology results and the availability of compatible blood and blood products? See §493.1109 or §493.1109(a). When compatible blood or blood products are not available, how is this information reported to the medical or nursing staff? See §493.1109(f). How has the laboratory assured that requisitions are completed for type and screen/crossmatch, including the correct patient identification and other required information? See §493.1105.
	Subpart K: Quality Control The laboratory meets all of the quality control requirements specified in §493.1201 through §493.1285.	Guidelines: See Appendix C, §§493.1201 to 493.1221 and §§493.1269 to 493.1285. Review the specific requirements for immunohematological testing that include the requirements cross-referenced from the FDA requirements for blood banks and transfusion services. See Appendix C, §493.1271. Probes: How does the laboratory ensure that patient identifier tags are securely fastened to the compatible units of blood? See §493.1273(d). What procedures are followed for issuing blood and blood products, including the positive identification of the patient and the blood or blood product(s)? If the blood bank is not staffed by laboratory personnel on a 24-hour basis, what provisions have been made for issuing blood and blood products? See §493.1273(d).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		How does the laboratory maintain a history of previously tested blood bank patients? See §493.1107. If bacterial contamination is suspected, how does the laboratory investigate the suspected units? See §493.1279. How does the laboratory investigate the possibility of disease transmission, e.g., hepatitis, malaria, from blood or blood products? See §493.1271. What samples of patient specimens and donor units does the laboratory have available to perform transfusion reaction investigations? How long are these samples maintained? See §493.1283. What records does the laboratory maintain of final disposition of blood and blood products including returned or unused blood or blood products? See §493.1107. How and when was the laboratory notified of the suspected transfusion reaction? See §§493.1279 and 493.1285. When a transfusion reaction is suspected, who is responsible for obtaining immediate specimens, e.g., blood, urine, plasma? See §§493.1279 and 493.1285. What happens to a unit if it is not acceptable upon visual inspection by laboratory or nursing personnel? See §493.1275. What procedures are followed for the release of blood or blood products in emergency situations? See §493.1269(a).
	Subpart M: Personnel As part of the Condition of participation at §482.27 of this chapter, a hospital's laboratory must provide personnel to direct and conduct the laboratory services. See Part 493 Subpart M-Personnel.	Guidelines: See Appendix C, §§493.1403 - 493.1495 (Personnel for laboratories performing moderate and/or high complexity testing). Guidelines: The laboratory personnel who collect, test and issue the unit have responsibility for correctly identifying the blood and blood products. Only a qualified person who understands the importance of blood bank protocols and adheres to them is allowed to collect patient samples and perform tests. If possible, observe whether personnel are competently performing procedures. See §§493.1425 and 493.1495. Probes: How does the laboratory ensure that personnel have the appropriate qualifications (training and experience) necessary to perform duties related to transfusion services? See §§493.1423 and 493.1489.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		How has the laboratory assured that an adequate number of qualified personnel are available on a twenty-four hour basis to perform testing? See §§493.1407(e)(10) and 493.1445(e)(11). In what situations are personnel expected to notify and consult with the supervisor (general and/or technical) and/or laboratory director? How are personnel made aware of the situations requiring notification? See §§493.1407(e)(14) and 493.1445(e)(15).
	Subpart P: Quality Assurance The laboratory meets all of the requirements specified in §493.1701.	Guidelines: See Appendix C, §493.1701. Review: o Quality assurance procedures, including those for reagents and equipment checks; o Adherence to the procedure manual for each significant step in the testing procedure, including the identification of the personnel performing each test procedure; o Records of other transfusion reactions and any other work-ups; o Any changes in procedures initiated by the laboratory; o All remedial actions, including changes in procedures or policies, inservice training, dismissal, transfer, or resignation of employees, etc., to ensure that the actions reported to FDA or HCFA have been instituted; and o The information submitted to the FDA and compare it with the documentation available in the laboratory, medical records and other record storage areas. Probes: How has the laboratory's policy/procedures/operations changed due to the transfusion death? Are these changes adequate to alleviate a similar situation? See §§493.1701 and 493.1717. Has the laboratory thoroughly studied the entire blood bank operation to determine if other areas of operation need change or correction to alleviate other possible reactions? See §§493.1701 and 493.1717. How has the laboratory handled any discrepancy between pre-transfusion testing and transfusion reaction work-up? See §493.1705(c) If no cause has been determined for the transfusion reaction, how has the laboratory assured that all possible causes of transfusion reaction were investigated? See §493.1701.
A295	**§482.55 Condition of participation: Emergency services.** The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A296	(a) Standard: Organization and direction. If emergency services are provided at the hospital--	
A297	(1) The services must be organized under the direction of a qualified member of the medical staff;	
A298	(2) The services must be integrated with other departments of the hospital;	
A299	(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.	§482.55(3) Guidelines: Policies and procedures governing emergency care, including the transfusion of blood and blood products, must be established and revised when necessary by the medical staff.
A300	(b) Standard: Personnel.	
A301	(1) The emergency services must be supervised by a qualified member of the medical staff.	
A302	(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.	§482.55(b)(2) Guidelines: If the transfusion reaction occurred in the emergency room, determine whether adequate medical and nursing personnel qualified in emergency care were on-duty.

CROSSWALK OF DEFICIENCY TAGS FOR TRANSFUSION FATALITY INVESTIGATIONS IN NON-HOSPITAL ENVIRONMENTS

When investigating a transfusion-related fatality, perform the inspection using the CLIA guidelines for laboratories, along with the appropriate regulations/survey guides for the facility involved.

The following chart is a guide for investigating a fatality in a Medicare/Medicaid facility other than a hospital. The deficiency tags listed in the example for a hospital investigation have been crosswalked to deficiency tags for ESRD facilities (V), long-term care facilities (F), and HHAs (G). They may not represent absolute correlation, but are to provide some direction if a transfusion-related fatality occurs in one of these types of facilities. Contact the RO if additional information is needed.

HOSPITAL TAG	LTC TAG	HHA TAG	ESRD TAG
A011	F492	G116	V61
A012	F492	G117	V62
A016	F493	G127	V65
A017	F493	G132	V65
A022	F495	G133	V65
A026	F309	G157	V66
A030	F316	G157	V66
A044	F511	G142	V82
A045	F511	G145	V82
A046	F511	G145	V82
A050	F537	G152	V281
A051	F539	G233	V281
A052	F539	G234	V281
A054	F538	G235	V281

HOSPITAL TAG	LTC TAG	HHA TAG	ESRD TAG
A058	F539	G236	V281
A059	F508	G120	V87
A075	F353	G137	V144
A076	F354	G137	V144
A077	F355	G140	V146
A087	F425	G162	V123
A088	F425	G162	V123
A089	F425	G162	V123
A090	F425	G162	V123
A091	F425	G162	V123
A092	F425	G163	V120
A093	F425	G163	V120
A094	F426	G163	V113
A095	F270	G226	V97
A101	F271	G226	V98
A102	F272	G226	V98
A103	F272	G226	V98
A104	F272	G226	V98
A105	F272	G226	V98
A106	F286	G226	V98
A107	F271	G226	V98

HOSPITAL TAG	LTC TAG	HHA TAG	ESRD TAG
A108	F272	G226	V98
A109	F272	G226	V98
A110	F272	G226	V98
A111	F272	G226	V98
A112	F280	G226	V98
A113	F272	G226	V98
A145	F511	---	V158
A146	F511 F512 F513	---	V158
A147	F511	---	V158
A148	F515	---	V158
A295	F395	G127	V84
A296	F395	G127	V84
A297	F395	G127	V84
A298	F395	G127	V85
A299	F395	G130	V85
A300	F395	G201	V86
A301	F395	G201	V86
A302	F395	G201	V86